# The Ethics and Governance of Dual-Use Synthetic Biology within the United States and the United Kingdom (2003 - 2012)

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**Abstract**

This thesis examines the emergence and governance of dual-use concerns associated with biotechnological innovation. Previous work has engaged with various facets of the dual-use issue from a wide range of theoretical perspectives. This includes, for example, the study of the dual-use issue as an ethical dilemma facing the scientific community (Miller and Selgelid 2007) and as a challenge to international arms control and non-proliferation regimes directed at biological and chemical weapons (Kelle, Nixdorff, and Dando 2006). Work in this area has also included educational (Rappert 2009) and other types of 'active research' (Rabinow and Bennett 2012) approaches, which have focused primarily on the scientific community. A key gap in this literature is the absence of comprehensive explanatory frameworks which address how and why governance initiatives are developing in national contexts, which could lead to clearer understandings of the scope and prospect of dual-use governance.

To this end, this thesis takes a comparative case study approach to characterise the emergence of dual-use governance regimes directed at the nascent techno-scientific field of synthetic biology. The work focuses on developments in the emergence of the field in two national cases studies; the United Kingdom and the United States of America. Empirically, the work draws upon several types of source material, including elite interviews as well as primary and secondary document analysis. In theoretical terms, academic debates about constructivist approaches to the study of securitization processes are utilized in order to help refine the analytical framework developed within this study.

This thesis represents the first substantive comparison of UK and US approaches to the governance of dual-use aspects of cutting-edge life science research and biotechnology. It identifies and characterises four key domains of dual-use governance at national level. Further to this, the work traces the various impacts of these domains on the emergence and

scope of dual-use governance in the case of synthetic biology in a US and UK context. In particular, this work reveals the role that existing laboratory safety and security regimes play in defining the scope of dual-use problems. It also identifies a number of attempts within the New and Emerging Science and Technology domain to move beyond these restrictive framings. Analysis reveals a series of challenges facing such initiatives which can be explained with reference to the institutions and norms within the key domains of governance as well as the relationship between these domains.

This work also reveals the extent to which dichotomous presentations of bottom-up verse top-down governance options represent a crude understanding of the politics of dual-use issues. In particular, analysis reveals how key aspects of the synthetic biology community, scientific institutions and industry have played a fundamental role in shaping the scope and nature of government responses to dual-use concerns in relation to certain dual-use issues associated with the field.

Finally, this thesis also demonstrates, through the utilisation of two policy process heuristics, that securitization theory could benefit greatly from further engagement with policy theory, particularly in the context of analytically eclectic research in the context of the study of non-traditional security issues.

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## Chapter One: Introduction and Thesis Outline

## 1.1 Introduction

Every so often, a story appears in the popular press which discusses the prospect that a specific scientific breakthrough or technological development might be misused by terrorists, criminals or governments. Often, such concerns exist as a vague anxiety and are accepted as an unwelcome and often unpreventable consequence of progress. Occasionally however, certain concerns are understood to go beyond the pale, to the extent to which they beg the question; should certain research and technology be prohibited, censored or otherwise controlled in the name of security?

Over recent decades, some aspects of cutting-edge biotechnology and life-science research have been discussed in such terms. This has included research which demonstrates how to make pathogens more transmissible and more deadly. It has also included new and emerging technologies which may make it easier so synthesise tightly regulated pathogens. Such research and technology is often said to have 'dual-use' potential. This is in the sense that it could conceivably benefit humanity but could also contribute to the risk that biology will be used to cause harm.

The dual-use issue can be conceived in ethical terms. There are two basic approaches to thinking ethically about the issue. The first approach prioritises the identification and quantification of risks and benefits in decision making. Within this approach the dual-use issue is often discussed in terms of the need to balance the imperatives of security and scientific progress. Some dual-use concerns involve potentially catastrophic and irreversible consequences, an anxiety which has long precedent in the societal assessment of science and technology. For example, it is at the root of current concerns that scientists could create self-replicating nano-machines which could envelope the whole world. This type of anxiety was

also at the heart of fears that the first nuclear tests could set fire to the sky. The emphasis on consequences, lends its self to questions about the need for foresight and precaution.

A second approach to thinking about dual-use issues relates to culpability. This type of thinking lends itself to questions about who, and to what extent, people and institutions are responsible for the negative consequences of innovation. It also involves thinking about how these responsibilities should be discharged.

Both types of consideration are brought to mind in an often quoted interview[1] given by Julius Robert Oppenheimer, a prominent contributor to the Manhattan project. Speaking 20 years after witnessing the detonation of the first atomic bomb he recalled:

> 'We knew the world would not be the same. A few people laughed, a few people cried, most people were silent. I remembered the line from the Hindu scripture, the Bhagavad-Gita. Vishnu is trying to persuade the Prince that he should do his duty and to impress him takes on his multi-armed form and says, "Now, I am become Death, the destroyer of worlds." I suppose we all thought that one way or another.'

Yet, innovation is a collective and societally embedded process. Our eye is often drawn to those 'actually there' at those (often) mythical moments of creation or discovery. However, this issue goes beyond the responsibilities of researchers. These responsibilities also extend to those institutions which support and govern innovation. This then involves broader reflection upon the appropriate relationship between innovators and broader society.

Indeed, when I was first exposed to discussions about the dual-use life sciences I remember feeling frustrated with some of the academic and policy literature which focused on the ethical responsibility of individual research teams involved in controversial research. What interested me, was the broader political context of these discussions. Specifically, I was interested, in question of why some contemporary and foreseen science and technologies were being discussed as being dual-use in the first place; where as others were not. More

[1] This quote came to notoriety when it appeared the documentary *The Decision to Drop the Bomb* (1965), produced by Fred Freed

fundamentally, I was also interested in the specific purposes and consequences of dual-use governance discussions and initiatives. I was also vaguely aware at the time, that there was some variance in how responses to dual-use concerns were developing in different national contexts. As early as the mid-2000's, comparisons were already being made between US and European approaches to dual-use issues in innovation in both academic and policy literature. This comparison then, seemed to be a good starting point to think about the broader political context which gave impetus and significance to dual-use discussions. In the US context, it appeared that dual-use issues were being taken much more seriously as a homeland security threat. In particular, the huge Bush era investment in biodefense at the time, was being associated with conflicting narratives which framed such investment as both a source and response to dual-use issues. In contrast, within the UK, it seemed as though the government was being less proactive in this issue area, and felt comparatively tranquil. Such contrasts, in the context of an absence of in-depth analysis of the politics of dual-use issues across national contexts, motivated me to develop a clearer understanding of the key factors shaping the emergence of policy.

The focus of the thesis further developed as I began to examine the way in which the emerging field of synthetic biology was being discussed as a source of dual-use concern. Importantly, these discussions were also supplemented with a range of policy initiatives, which were emerging from government, industry, as well as the scientific community. As I was interested in how dual-use concerns emerged, and the extent to which concerns related to governance responses, the field seemed a natural focal point for a comparative case study.

It was apparent however, that addressing such questions required the development of a suitable analytical framework to help focus and structure comparative analysis. As there had been no substantive attempts to do this within the academic literature, I was left with the task

of finding a suitable framework. My focus was initially drawn to frameworks of ethical and risk analysis. However, I felt that deductively applying such established approaches would fail to capture the broader political context of the issue area. For me then it made sense to utilise a more inductive approach to the study of the issues area. It was about this time that I was introduced to theoretical debates occurring within the International Relations and Security Studies literature. In particular I became interested in main-stream constructivist approaches to the study of political processes. This then, would form the bases of my decision to focus on Securitization Theory; a sub-field of Security Studies. What followed was an in-depth analysis of the governance of dual-use aspects of synthetic biology, which involved interviewing experts, analysis of policy documents as well as attendance to a number of conferences.[2]

In the following section, I introduce the structure of this thesis.

[2] This included meetings organised as part of the project my thesis was embedded in. These took place at the Australia National University and Bradford University. It also included a number of international conferences on dual-use issues which were organised primarily by scientific organizations and academics. Added to this I also attended three international conferences on Synthetic Biology. This included Synthetic Biology 5.0 held at Stanford University in Summer 2012.

### 1.2 Thesis Outline

In chapter two the central focus of this thesis is outlined. This includes a general introduction to the issue area, previous academic research, as well the aims of the thesis. It is argued that it is important to distinguish between four domains of dual-use governance. Each of these domains is associated with a largely discreet set of institutions, interests and styles of politics. This chapter outlines specific aspects of this broader political context which are important in understanding the governance of dual-use issues. The chapter also discusses the potential value and limitations of conceptualising the dual-use issues as a complex type of risk.

In chapter three, an analytical framework is developed in order to provide a clearer understanding of how dual-use issues emerge and are responded to. The framework builds primarily on insights from securitization theory. Scholars in this field have been reflecting on the politics and practice of security for over decade and a range of analytical concepts are identified for use in the task in hand. One key part of this framework is a distinction between the concepts of primary and secondary securitization.

In chapter four, the field of synthetic biology is introduced as a techno-scientific field of dual-use governance. The field of synthetic biology was chosen as a focus because it was the field that had been associated most prominently with dual-use concerns. Within this chapter there is an introduction to the way in which science and technology are framed as part of dual-use problems.

In Chapters five and six, there is an in-depth analysis of the emergence of, as well as responses to, concerns about dual-use aspects of synthetic biology in a US and UK context. Analysis focuses on the current state, as well as prospect, of dual-use governance in these national contexts.

In chapter seven, there is a structured analysis of the case studies, before conclusions, and future research questions are outlined in the final chapter.

## Chapter Two: The Politics and Governance of Dual-Use Issues

### 2.1 The Pre-History and Emergence of the Dual-Use Concept

Historically, human inquiry has often led to unforeseen findings that have had immediately obvious applications as military technologies. For example, gunpowder was supposedly discovered by *'Taoist alchemists looking for elixirs of love'* (Reid 1969, 1). State militaries have also long possessed the inclination, expertise and resources to identify and harness seemingly benign discoveries and technologies in the development of new weapons. For example, the first manned air balloon flights of 1783 spawned a host of both civilian and military projects to put the new technology to use. Various militaries in the early 1800s experimented with hot-air balloons as bombers, as well as for observation, communication and transportation (Holmes 2009, chap. 8). Likewise, military projects have been understood to have contributed to a host of civilian applications, often referred to as military spin-offs; an often stated example of this is the internet.

Particularly since the Second World War, exchanges between military and civilian science have been actively encouraged, as this was often understood as making good economic sense. Bearing this history in mind, it is unsurprising that the term ‘dual-use’ hasn’t always had the negative connotation that it has today (Miller, Selgelid, and Bruggen 2011, 8–11).

The close relationship between military and civilian innovation has also been understood to complicate efforts to control sets of technologies for security reasons. This includes the prevention of the proliferation of ‘taboo’ weapons, which are weapons against which there are stigmas regarding development and use. In the context of nuclear, chemical and biological arms control there are technologies and materials which are necessary for both maleficent and benign applications. For example, nuclear reactors as well as fissile material can be used to produce nuclear power, as well as nuclear weapons. In this context, the term ‘dual-use’ refers

to technologies that are understood to have both legitimate peaceful (civilian) and illegitimate or controlled (military) applications within the international community. Since at least the end of the Second World War states have attempted to control who had access to dual-use technologies, primarily through systems of licensing and the harmonisation of export controls. Up until around the turn of the 21st century much less consideration was given by states to controlling civilian research and emerging technology because of the potential for hostile misuse. There is, however, a precedent of such controls, especially in times of heightened economic competition or conflict (Relyea 1994).

This history suggests that there is certainly nothing new about the idea that science and technology can be used for dual-purposes, which may be understood to be both 'good' and 'bad', and may at times need controls. But never has such a broad range of both research and technology (both existent and foreseen) been discussed in terms of misuse potential. Added to this, never have such a broad range of stakeholders concerned themselves with the governance of this issue. In this respect, the development of dual-use governance over the past decade in relation to the life sciences can be understood as an unprecedented project.

Explanations for these developments include: increased levels of anxiety, particularly within the US security community about the threat of bioterrorism and biological WMDs, increased concerns about emerging and re-emerging infectious disease, understood failings of an inadequate international biological arms control regime as well as increased stakeholder engagement with the Biological and Toxin Weapons Convention (BTWC) regime (Fidler and Gostin 2008). Added to this, developments in scientific and technology (i.e products and underlying systems of innovation) can also generate and galvanise security concerns (Kelle, Nixdorff, and Dando 2006; 2012). Furthermore, as societies have become more cognisant of the societal impact of scientific and technological developments, there has been increased

pressure upon those that support innovation to evaluate, minimise and communicate risks (Jasanoff 2005). This may also provide an explanation for the increased levels of dual-use concern in relation to new and emerging science and technology.

Taken together, these observations point to the idea that the emergence of dual-use concerns is not just dependent on new security fears or technological developments, but is rather the result of more complex political processes. This suggests that while misuse concerns may be as old as science, today's dual-use issues represent unprecedented policy challenges. The following section provides an overview of the modern manifestation of the dual-use issue in relation to the life sciences.

### 2.2 The Emergence of Dual-Use concerns about the Life Sciences in the 2000s

In the early 2000s, several pieces of life science research involving pathogenic viruses were given public and institutional attention as examples of dual-use research that represented a cause for concern. The first group of examples related to the concern that published research could provide terrorists with the information required to synthesise pathogens; providing a novel route to acquisition. One of these experiments demonstrated how to resurrect the 1918 Spanish Influenza virus from frozen human remains (Tumpey et al. 2005). Another experiment demonstrated how to construct the Polio virus utilising mail-order polynucleotide sequences (Cello 2002).

The second group of examples related to the concern that the manipulation of existing pathogens that may lead to the development of super-viruses. Such concerns were expressed in relation to bioterror scenarios, but also in relation to much better resourced, nationally funded bio-weapon projects. An example of this was an experiment which accidently uncovered the means by which to make the mouse-pox virus (a relation to the human

smallpox *Variola* virus) more virulent (Jackson et al. 2001). This kind of experiment became a focus of concerns about the development of new biological weapons of terror and mass-destruction.

The examples above are commonly used for illustrative purposes; however, at least a dozen specific experiments are publicly known to have been reviewed for dual-use potential internationally in the period 2001-2009 (Zmorzynska et al. 2011, 375). Since this time, two experiments relating to the manipulation of the *avian influenza* virus[3] have also been subject to emergency reviews at national and international institutions (Implementation Support Unit 2011 and Edwards, Revill, and Bezuidenhout 2013). Reviews of specific pieces of dual-use research of concern have all tended to focus on the specific aims, results and potential risks and benefits of the research, as well as the risks and benefits of stifling such research (Zmorzynska et al. 2011, 374). Since the emergence of the dual-use issue in 2001**,** debates about dual-use research have sometimes become entangled with discussions about the controls of foundational technologies and research agents. This includes most notably technologies that can be utilised to synthesise polynucleotide sequences,[4] which may increase the availability of 'select-agent' pathogens[5] to people who are not subject to existing systems of safety or security oversight. The term 'select-agent' pathogens is used here to denote a range of infectious agents which are controlled through various governance mechanisms because of their historic or foreseen utility as biological weapons, as well as the serious risks associated with the accidental release of pathogens from laboratories. This includes a wide

3 Commonly known as the bird flu virus or the H5N1virus, which is the name of a specific virus strain.

4 This includes various forms of genetic material found in viruses, bacteria, plants and animals ranging from very short single or double stranded DNA molecules, all the way up to gene-length and genome length sequences. These molecules are fundamental to the development and functioning of the basic biological processes which constitute biological organisms. For a great accessible introduction see Noble (2006).

5 Particularly viruses, which usually comprise of genetic material, as well as a protein and lipid 'coat'. The latter two components are essential to the infection process, as well as the survival of the virus in its *virion* state (i.e example when virus exists as a single infective particle and is not inside a host cell, utilising the cells resources to reproduce)

range of pathogens which can infect livestock, crops and humans.

Distinctions can be made in relation to the scope and focus of current dual-use discussions; specifically there have been three focal points of academic analysis and policy discussion. These are outlined below:

Dual-use Research

The traditional understanding of scientific research is that it involves a collection of institutions and practices which contribute to the development of understanding and practical knowledge. Within most conceptions of science, there is an assumption that 'applied' and even 'basic' research can contribute to the development of technologies. The term 'dual-use research' is usually used to denote specific scientific experiments, or else categories of scientific research, which could be foreseeably misused. In 2004, an influential report (National Research Council 2004) identified seven types[6] of research as being of particular concern. This included research which makes pathogens more deadly, transmissible or demonstrates how to make pathogens more practically viable as a weapon. Since this publication, discussions about the governance of dual-use research have focused on a series of key intervention points in the research process between the funding and publication stage. The first has been the need for vetting and monitoring those with access to dangerous laboratory pathogens. The second has been the need for laboratory safety and laboratory biosecurity in order to prevent accidents and theft. The third has been the need for responsible publication practices within the scientific community, and where necessary, censorship. This

[6] Experiments of concern would be those that: 1) would demonstrate how to render a vaccine ineffective; 2) would confer resistance to therapeutically useful antibiotics or antiviral agents; 3) would enhance the virulence of a pathogen or render a non-pathogen virulent; 4) would increase transmissibility of a pathogen - this would include enhancing transmission within or between species; 5) would alter the host range of a pathogen; 6) would enable the evasion of diagnostic/detection modalities; 7) would enable the weaponization of a biological agent or toxin.

is based on the concern that scientific papers may provide useful information to would-be bioterrorists. Finally, discussions have focused on the need for ethical, safety and security assessment in relation to 'high-risk' pathogens from as early as the funding stage in the research process (National Research Council 2004).

Dual-use Technology

Traditionally, technology is understood to include physical and abstract tools which are developed to solve real-world problems. Such technologies may have direct applications, or else provide the basis for the development of technologies with other applications (facilitating technologies). Traditional models of technology generation place emphasis on the role of the state and privately funded research in underpinning technological developments.

The term 'dual-use technology' is generally used to refer to existing technologies, as well as emerging technological capabilities, which could foreseeably make it easier for terrorists to access, produce and weaponize biological agents. In relation to the concept of dual-use technology, there has been a particular focus upon technologies which have been understood to contribute to the de-skilling of processes needed for production and manipulation of pathogens. This trend is also associated with the increasingly broad dissemination of many biotechnologies as they become cheaper and easier to use ( for example Tucker 2012).

Dual-use Techno-science

The term techno-science has a complex intellectual heritage, and has often been used to denote changes and trends within scientific practice, as well as specific normative stances on the role of science in modern societies. Recent discussion about dual-use techno-science emphasises the non-linear nature of innovation, the co-productive nature of society and science, and the increasing role of politics and values in shaping research priorities (Schmidt

et al. 2009). Within this understanding, greater emphasis is placed on the contexts in which innovation occurs, and the political process which give these developments significance. There is also greater emphasis on anticipatory and precautionary approaches to dual-use issues (for example Kelle 2012).

Each of the above facets of innovation has become central to discussions about the governance of dual-use aspects of the life-sciences. A key question within this thesis is how each of these facets has emerged as a focal point of discussion and how solutions to dual-use issues have been developed, tabled and implemented. In the following section, there is a more in-depth introduction into this central line of enquiry.

### 2.3 Studying the Manifestation of Dual-Use Concerns in the 21st Century

In the previous section, it was argued that the dual-use issue at its most fundamental revolves around the concern that scientific and technological progress may be utilised for both beneficial and nefarious purposes. There have been numerous examples of research and technology being discussed in terms of dual-use potential in the previous decade, particularly within the US and Europe. This includes research which revealed new ways to make pathogens more deadly, and technology which makes it easier to produce tightly controlled agents traditionally associated with bioweapon programmes. This thesis examines the political context of emergent debates about the governance of dual-use aspects of new and emerging science and technology. The research is carried out with a specific focus on dual-use governance activities related to the techno-scientific field of synthetic biology, a field which has been most prominently associated with dual-use discussions in the past decade. The analysis focuses on two national case studies: the UK and the US.

It is widely understood that national security concerns and responses to the bio-terrorist

attacks of 2001 are essential to understanding the emergence of the dual-use issue as a 21st century challenge (McLeish and Nightingale 2007). However, what is less clear in academic analysis is how these developments have impacted upon the governance of specific areas of cutting-edge science and technology. This research provides new insights into the process through which dual-use issues emerge as governable problems by contrasting the political processes that surround the emergence of dual-use policies in the US and the UK. The US and UK provide for an interesting comparison, due to their contrasting responses to the threat of bioterrorism in the post 9/11 world (Lentzos and Rose 2009).

This thesis will provide researchers and policy shapers with a means to understand the underlying political processes which have impacted upon the emergence of dual-use governance within these states.

Thesis rationale

The development of the central line of enquiry within this thesis is based on several premises. The first assumption is that the emergence of dual-use issues on policy agendas is underpinned by:

a) *The emergence of fears about terrorism, specifically bioterrorism, in both public and policy circles, with a particular focus on the threat from non-state actors*[7]

This has resulted in a wide range of responses at national and international level

[7] The literature on this issue is sizeable and wide ranging. However, key journals in which there has been discussion of the emergence and response to the threat of bioterrorism are the *Journal of Bioterrorism and Biodefense* (2010-) and *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* (2003-). The issue has also emerged in several infectious disease, clinical micro biology journals – most notably the *Journal of Emerging Infectious Diseases* (from 1998 onwards). The issue has also appeared in security and non-proliferation journals such as *Survival* (from 2007 onwards). In addition, there have been a series of books and edited volumes which have tracked the history of the emergence of the issue, notably Carus (2002), also in relation to public health (Patel and Rushefsky 2005, chap. 8) (Mellehovitch 2004) (Fidler and Gostin 2008)(Koblentz 2009)

focused on predicting, preventing and mitigating the risk of biological attacks from terrorists and states. This development has also been reflected in the broadening agenda of the BTWC as an international regime, in which a greater emphasis has been placed on the threat of sub-state terrorism over the previous decade.

b) *The dominant pre-conception that we are currently experiencing a rapid period of development in the technical and intellectual capabilities within the life sciences*

These developments are also associated with expanding and changing modes of technological innovation and use. This has been understood to involve the ever wider dissemination of scientific and technical knowledge, which is coupled with a 'de-skilling' dynamic – meaning that less capital, training and practical life science expertise is required to use and even develop cutting-edge bio-based technologies (Schmidt 2008; Tucker 2011). This has been understood by some policy shapers to present a challenge to existing governance frameworks directed at safety, as well as those directed against the misuse of science and technology (Bowman et al. 2013, 63).

c) *Changes in the relationship between science and democratic societies*

These developments have led to new collaborative assessment regimes directed at innovation and cutting-edge technology. These regimes have involved a wider range of stakeholders than ever before, which has led to a greater emphasis on precautionary approaches and 'up-stream' engagement with the research and development process. This approach is often contrasted to more 'traditional' approaches of responding to the risks generated by emerging scientific and

technological products on an *ad hoc* base, through the application of pre-existing risk management frameworks.[8]

The second set of assumptions relate to the governance of new and emerging science and technologies. The development of emerging governance frameworks at a national level has been complicated a broad range of stakeholders engaging with the issue, which is prone to political contestation. This has generated a certain 'fluidity' in the development of dual-use governance in national contexts. However, despite its novelty, dual-use governance is still best understood with reference to pre-existing ideational and institutional frameworks that have dominated the governance of science and technological risk, and national security.

The third set of assumptions relates to the appropriate level of analysis in dual-use governance. While the improvement of dual-use governance is generally understood to require international responses, national level policy development and implementation remains central to the oversight of dual-use issues. This is typified, for example, by the main international regime tasked with preventing the development of biological weapons (the BTCW), which is primarily dependent on national level implementation. As a result, there is a focus on national level policy initiatives within this work; this means that international initiatives and actors are only referenced when these factors are understood to be of direct relevance to domestic level policy.

A final key set of assumptions is that the politics and practices of security have been of some importance in the development of dual-use governance, but that the specific significance of these factors remains under theorised. By giving closer scrutiny to this area, it may be possible to reveal trends in the governance of the issue which are not currently given

[8] In relation to biotechnologies See (Jasanoff 2005). In relation to convergent biotechnologies such as Synthetic biology see (M. Schmidt et al.. 2009) Also with relation to techno-sciences more generally see (Kaiser, Maasen, and Kurath 2010a)

attention in the dual-use governance literature.[9]

This leads to a line of enquiry which can be formulated as a research question:

> *To what extent are the conceptions, practices and politics of security relevant to understanding the governance of dual-use aspects of new and emerging science and technology at national level in the UK and in the US?*

In answering this question there are three interrelated focal points of analysis:

1. The *'subject' and 'scope'* of dual-use governance. This involves identifying which specific aspects of techno-scientific fields have been constructed as presenting a dual-use concern and the relationships between these concerns and pre-existing discourses and practices. These questions reflect a central line of enquiry for scholars such as Vogel, who has examined the impact of the framings of science and technology on our understanding of how threats involving bioweapons are socially generated. There is also a need to examine the role of constructed security threat scenarios within this process (Vogel 2006; 2008a; 2012), as well as pre-existing approaches to the identification and management of risks.

2. The *'politics' and 'practice' of* dual-use governance. This involves examining the generation, development and implementation of policy initiatives, and their political context. In particular there is an emphasis on explaining why certain approaches to conceptualising and addressing dual-use issues are adopted, and the extent to which such approaches are successfully implemented.

[9] The discussion of security and securitization have been common in relation to dual-use governance. Notable examples include McLeish and Nightingale 2007, Bruggen 2012, Lentzos 2006 and Lentzos and Rose 2009. The discussion of the securitization of aspects of public health is also relevant to understanding dual-use governance activities Kelle 2007, Davies 2008, Jin and Karackattu 2011 and Cook 2010. However, there has yet to be a comprehensive securitization analysis of the governance of dual-use aspects of new and emerging science and technology.

3. The '*nature*' and '*prospect*' of national approaches (i.e. styles of governance and politics) to the issue of dual-use governance. In particular, there is an emphasis on the role of risk assessment rationales within dual-use governance. Such rationales are interesting because there is some disagreement about the wisdom and prospect of risk management in the context of the governance of the dual-use issues (Fleming 2007; Kelle 2012). Attention is also given to the emergence of coalitions between stakeholders, as well as to new channels of policy development.

Now that the reader has been introduced to the scope and purposes of this thesis, the remainder of the chapter is dedicated to explaining the emergence and nature of the dual-use issue as a policy challenge in the US and UK context.

### 2.4 The Four Domains of National Dual-use Governance

Dual-use issues have generally been understood to require a web of responses from a wide range of stakeholders (Rappert and McLeish 2007). The rise of 'governance webs' within the dual-use discourse reflects a broader trend within the BTWC, the international regime tasked with preventing the development of biological weapons (McLeish and Feakes 2008, 6). Within this understanding there tends to be enthusiasm, as well as optimism about the extent to which collaboration between institutions can foster effective policy development and implementation at national level. However, such a perspective risks neglecting the distinct '*political and normative frameworks*' as well as distinct '*styles of reasoning*' (Fidler and Gostin 2008, 12, 15) which inform the decision making of stakeholders in this area at national level. Such differences can hinder the development and implementation of policy, even if there is an agreement between stakeholders that a response to the issue is required. This means that it is important to map the broader political context which informs the way in which different actors engage with the dual-use use issue as a political problem.

In the following section the various institutions, stakeholders and dominant governance paradigms are introduced. In order to structure the comparison between the UK and the US, four 'domains of governance' have been identified. The term 'domain of governance' refers to largely discreet areas of governance which comprise of normative and legal frameworks, institutionalised processes of reasoning and decision-making, and political constellations of actors. This type of conceptualisation of the institutions and ideational landscape of emerging fields of governance has already been utilized in the definitive work of Fidler and Gostin (2008), who examined changes in the way in which infectious disease is governed in the US context. Within this work, they pay particular attention to the role of norms and institutions found within the generally discreet domains of public health and national security governance in the emergence of new initiatives directed against the threat posed by infectious diseases in the 21st century. This work served not only to highlight the historical and institutional context in which governance emerges, but also allowed for the conceptualisation of the practices, underlying rationale and overall purposes of the broad range of activities directed at the broad issue of infectious disease.

Within this thesis, the issue of interest is dual-use rather than infectious disease, and this has led to the identification of a different set of domains. The domains identified within this thesis are '*Biosafety*', '*Anti-terrorism*', '*Public Health*' as well as '*New and Emerging Science and Technology Governance*'. These domains of governance are now introduced in the UK and US context.

### 2.4.1 New and Emerging Science and Technology Domain

The societal assessment of New and Emerging Science and Technology (NEST) is often typified as involving the public and media discussion of controversial technology and research. Notable examples of technology which have received substantial attention include

human cloning, genetic modification technology and nanotechnology. However, NEST assessment involves a broader set of activities than public dialogue between scientists and wider society. For example, decisions and recommendations made by NEST ethics institutions (such as the US Presidential Commission on Bioethical Issues or the European Group on Ethics) have had very real impacts on the practice and regulation of science in relation to given issues such as stem cell research. In the following section, the domain of 'NEST assessment' is further elaborated.

Within both the US and Europe, state funded life science projects have increasingly had an Ethical, Legal and Social Issues (ELSI) aspect. The earliest project of this type was the Human Genome Project, which began in the 1990s. Within this project, 3% to 5% of the project budget was allocated to the study of these issues. In essence, ELSI projects associated with new and emerging fields have increased institutional capacity for social scientists, ethicists, lawyers, and Civil Society Organisations (CSOs) to engage with discussions about new and emerging technologies. The development of this practice can be explained with reference to the fundamental changes in the nature of scientific research that have occurred since the middle of the 20$^{th}$ century (Gibbons, Limoges, and Nowotny 1994). Gibbons et al. (1994) refer to the development of a 'Mode 2' of scientific production which has four characteristics:

- knowledge is increasingly produced in the context of application (as opposed to the production of 'pure' science, which may then be utilised in the development of applications);
- science increasingly draws upon theoretical elements from various fields;
- knowledge is produced in a wider variety of sites that ever before; and
- participants in science have grown more aware of the social implications of their

> work, just as society has become more aware of the way science and technology impacts lives (adapted from Jasanoff 2005, chap. 2).

Kaiser et al. (2010) argue that these developments have underpinned the emergence of 'assessment regimes' around new and emerging convergent techno-scientific fields over the previous decade. (Kaiser, Maasen, and Kurath 2010a, chap. 1). This includes, for example, nanotechnology, as well as synthetic biology. These regimes can be understood to comprise of a wide range of stakeholders who have applied a diverse set of assessment rationales to emerging fields. There are three central dimensions of these emerging regimes (based on categories developed by Kaiser, Maasen, and Kurath 2010a, xiii):

*Democratising dimension*

Since at least the Second World War there have been calls for the democratisation of innovation processes. This involves the development of political systems which allow society to engage with the evaluation of new and emerging science and technology. The extent to which these aims are aspired to and reached in contemporary NEST politics is of course contested. For example, there has been much discussion of how scientific developments should be communicated to the public, with many within the scientific community argue that there is a requirement to 'educate' the public about new and emerging technologies. This can be in contrasted to more participatory approaches which seek to make the scientific community more cognisant public concern and needs (for example Hagendijk and Irwin 2006; Bowman 2008; Nerlich, Elliott, and Larson 2009).

Despite the occasional charge that ELSI initiatives will always remain an exercise in 'talking-shop' public engagement, ELSI activities have inspired many actors and institutions from wider society to engage with the governance of new and emerging technologies, and this has

led to new institutions and forms of collaboration in relation to NEST issues (Kaiser, Maasen, and Kurath 2010a, xv). It is likely that the increased involvement of a wide variety of actors in techno-scientific fields, particularly in the early stages, may have had some discernible impact upon dual-use discussions.

*Anticipatory dimension*

The anticipatory element of NEST governance involves an emphasis on the evaluation of science and technology before its products are legion. Official (often government) bioethical institutions play a fundamental role in the evaluation of biotechnology. Bioethical analysis is often conducted in terms of how a specific aspect of a moral value system is conceivably impacted upon by a new invention. This value system could be centred on either the rightness or wrongness of actions in themselves (deontological) or by their consequences (consequentialism). Within recent decades, and in the US in particular, discussion has also focused on mid-level ethical principles, such as 'justice' or 'public beneficence' (Beauchamp and Childress 2001). Within European context in particular conceptions of precaution have also become predominant within the ethical discourse.

However, anticipatory discussions are not only restricted to official bioethical forums and discourses. A wide range of institutions and interest groups also exist which aim to impact on the emergence of policy in relation to cutting-edge fields (Jasanoff 2005, 28). Dual-use issues are a recent addition to concerns about biotechnology, which means that the political landscape of anticipatory governance is not well understood (Kelle 2012; Edwards and Kelle 2012).

*Innovation dimension*

Finally, there has been increasing societal attention to the idea of transforming innovation processes, rather than just seeking to better facilitate communication between scientists and the public. This is to make these processes more responsive to societal needs, and enable prp-active rather than re-active approaches to identifying and managing potential risks. This move 'up-stream' in the scientific development process has led to a greater focus on the practices and processes of scientific development, as well as increased attention upon the pre-emptive governance of emerging technologies. In recent years an increasing number of projects in fields such as synthetic biology have included an 'up-stream' element which have tended to involve anthropologists and STS scholars (Rabinow and Bennett 2012). It is conceivable that such projects may have local, and even national or international impacts on the emergence of dual-use governance regimes surrounding specific areas of science and technology.

Dual-use Nest governance in US and UK contexts

In the discussion of other governance domains within this thesis, existing literature has allowed for distinctions to be made between national styles of governance of dual-use issues. However, for several reasons it is important to remain tentative about US and UK styles of governance within the NEST domain in relation to dual-use governance. First, there is an absence of literature which has examined how dual-use issue have been incorporated into NEST governance activities. While it may be tempting to assume that dual-use issues are dealt with in identical ways to other issues on the NEST agenda in national contexts, it is already becoming clear that dual-use issues have not been neatly incorporated into existing NEST governance frameworks (Edwards and Kelle 2012, 6; Rabinow and Bennett 2012). Second, even if the dual-use issue can be understood to have been incorporated into existing NEST governance systems, NEST governance approaches adopted in relation to a given techno-scientific field are also contingent on the norms of dominant actors and the

institutional landscape, as well as historic and cultural factors (Jasanoff 2005, 17–22). This means, especially in the context of convergent technologies, that there is likely to be variance in NEST governance norms between different techno-scientific fields of dual-use concern.

For these reasons the NEST domain is characterised for the UK and US case studies with direct reference to the field of study, namely synthetic biology, in this thesis. This is in contrast to the other domains of dual-use governance, in which the nature of governance responses appear to be less contingent on the politics surrounding a specific techno-science.[10] An approach to structuring this comparison is outlined below.

Within the NEST literature, one approach to analysing the politics surrounding new and emerging science and technology has been to identify 'typologies' of NEST governance. Such typologies can be utilised for a variety of analytical purposes; within this thesis, however, they are utilized to help structure comparison. The typologies used in this thesis (introduced below) are taken from a European 5th framework funded project conducted by Rob Hagendijk and Egil Kallerud,[11] which involved case study research on EU countries. However, comparable typologies have been identified widely within the technology risk governance literature (Renn 2008, 385; Löfstedt and Vogel 2001; Jasanoff 1986, 79–83).

***Discretionary***: In discretionary governance, policy making takes place with virtually no explicit interaction with 'the public'. Decisions are taken with very little input to the policy process by any group outside of the institutions directly responsible for science and technology policy (essentially, government departments and closely related industrial and scientific bodies).

10 This is an issue which is subject to further in-depth discussion in later chapters.

11 http://www.stage-research.net/STAGE/index.html. Final report available at http://www.stage-research.net/STAGE/content/reports.html.

***Corporatist***: Within corporatist governance, differences of interest between stakeholders are recognized as inputs to processes of negotiation in which workable compromises are sought. The processes of negotiation take place within a closed or highly regulated space, so the decisive feature is the question of admission and recognition of legitimate stakeholders.

***Educational***: Educational modes of governance assume that conflicts or tensions regarding science and technology policy are founded on a lack of knowledge on the part of the public. Hence it is necessary to educate the public through dissemination of scientific (expert) knowledge in order to create an informed public of scientific citizens that understand the experts' assessment of the problems and possibilities of science.

***Market***: Market governance is based on the notion that science and technology can be governed through the economic mechanisms of demand and supply. The value of science comes from the surplus value created through its commercialisation and the general contribution to the generation of wealth in society. Scientific governance should be supportive of this potential. In this mode, the public participates as customers and consumers in a market when they make decisions about purchasing a product.

***Agonistic***: Agonistic governance takes place under conditions of confrontation and adversity, when decisions have to be made in a political context where positions are strongly opposed.

***Deliberative***: Deliberative governance rests on the ideal that governance of science can be based on strong public support deriving from a continuous public debate of, and

engagement with, science. Consensual agreements developed within the framework of the public sphere serve as foundations for legitimate policy decisions. In this mode, members of the public do not partake as consumers of science, but as scientific citizens.

Each of these approaches to the governance of science may have shaped the governance of dual-use issues. It is also possible to conceive of how the political contentiousness of the dual-use issue in either of the nation states may have impacted upon the adoption of a model at various points in time.

These typologies suggest that public engagement can be given a different level of priority within NEST regimes, with various motivations and styles of implementation. There may also be different understandings of the extent to which stakeholders should seek consensus over issues, and how this should be publicly discussed. Furthermore, all of the above are dependent on political conditions which can alter over time.

This suggests that, in the analysis of the development of dual-use governance at national level, close attention should be given to the nexus between NEST governance as well as to developments within other domains. In particular, politicisations of relationships between stakeholders, as seen in the biosafety domain in the US, can have resonating effects within the NEST domain. It may also be argued that the adoption of certain NEST approaches may impact upon deliberative processes in other domains, encouraging or restricting the range of stakeholders within the deliberative process of policy development. These themes are returned to in the analylitic and conclusive chapters.

### 2.4.2 Biosafety Domain

The term biosafety refers to principles and practices directed at preventing the unintentional release of biological organisms and toxins into the environment, as well as the protection of personnel working with dangerous organisms and other biological materials. States are required to implement biosafety policies under international health law, and also increasingly under agreements made in relation to international bio-security. This is outlined in the figure below:

| | WHO International Health Regulations (2005) | UN Security Council Resolution 1540 (2004) | Biological Weapons Convention (1972) |
|---|---|---|---|
| **Applicability:** | All 192 UN Member States | All 192 UN Member States | 163 States Parties |
| **Purpose:** | "to prevent, protect, protect against, control and provide a public health response to the international spread of disease…" | To prohibit **non-State actors** from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems. | To prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons |
| **Requirements:** | 8 core capacities "to detect, assess, notify, and report events" [Laboratory core capacity includes biosafety / biosecurity] | Domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, their means of delivery, and related materials | Any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons |
| **Entry into force:** | 15 June 2007 | 28 April 2004 | 26 March 1975 |
| **Mandated reporting / where / when:** | Status of implementation / WHO/*"As soon as possible but no later than five years from entry into force …"* | Status of implementation / 1540 Committee / *"without delay"* | None' "CBM voluntary reporting/ BWC ISU/ annually by 04/15 |
| | Biosafety / Biosecurity | | |

**Table 1 International agreements covering biosafety and biosecurity**

*From*: Bakanidze, Imnadze, and Perkins (2010)

An addition to this spectrum would also be the *The Cartagena Protocol on Biosafety* an agreement made under the convention of biological diversity which entered into force in

2003. However, biosafety policies have generally tended to be developed and implemented at national and sub-national level within the UK and the US.[12]

In the US as well as in the UK, existing biosafety law, institutions and practices have been understood to be central to the implementation of policies directed against the misuse of the life sciences. However, the politics of biosafety is quite distinct within these states. In the following sections, the biosafety domain is introduced in these national contexts.

Biosafety and the dual-use issue in the US

In the US, laboratory biosafety governance first developed in relation to classified biological research. Since the 1950s, biosafety information has been made available to the wider scientific community through a series of publications and conferences (Fleming 2007, 109). The Asilomar process also stimulated the emergence of biosafety governance activities during the 1970s in the broader scientific community. The process led to the publication of a set of voluntary guidelines for the physical containment of recombinant DNA molecules. In the 1980s two institutions within the Department of Health and Human Services (DHHS) would also collaborate in a consultation process that led to the development of a set of guidelines for worker safety as well as for public health in response to potential biohazards associated with the possession and use of pathogens (National Research Council 2004, 41–46). This included the development of a tiered categorisation system based on the hazards particular pathogens pose. The most dangerous pathogens, which includes many classic biowarfare agents, are referred to as 'select-agents'(Greenberger, Kovacs, and Mike 2010, 11).

[12] Although some aspects of UK biosafety policy can be understood to have been impacted upon by EC legislation, specifically the Environmental Protection Act of 1990, the so-called Green Bill 1990, which focused on the controlling the environmental release of GMOs. However this has also been implemented domestically through Health and Safety institutions.

Since the establishment of the select-agent system, the NIH has also taken on responsibility for the oversight of genetic engineering research. This responsibility has been discharged through encouraging the adoption NIH guidelines in all institutions (both domestic and international). In order to receive NIH support, institutions must establish an institutional biosafety committee (IBC) to ensure transparency and compliance with the guidelines. These committees must consist of at least five members, two of which cannot be affiliated with the institution which represents the interests of the surrounding community (National Research Council 2004, 35).

Private organisations, as well as non-NIH federally funded institutions, are not legally required to adhere to the NIH guidelines. However, some private organisations as well as federal agencies have voluntarily developed and registered their IBC's with the NIH. There are a series of motivations for this, including ensuring compliance to anti-terrorism law, as well as protection against private litigation (Knowles 2012, 50). There are also a series of other regulations concerning the handling of hazardous materials, specifically from the Environment Protection Agency and Department of Agriculture; however, these regulations focused on the transport of pathogens rather than research practices (Steinbruner et al. 2005, 23).

Within the US, concerns about bioterrorism created a large impetus for quick and decisive responses to the threat posed by the misuse of select-agents. As Atlas states:

> In only five years, the regulatory regime for possession of certain Microorganisms and toxins in the United States went from a permissive atmosphere, in which biosafety was the primary concern and the laboratory facility, not the individual scientist, the focus of regulation, to a situation in which biosecurity is of prime importance and individuals face criminal sanctions if they violate any of the restrictions outlined in the USA Patriot Act or the Bioterrorism Act of 2002 (Atlas 2005, 9).

Lack of faith in the existing biosafety regime also impacted upon discussions of dual-use research oversight. In 2003, the NRC report entitled *Biotechnology Research in the Age of Terrorism* identified the IBC system as a mechanism by which it was possible to review the misuse potential of any experimental of concern. The ability and suitability of these institutions in discharging this role has been a source of political contention within the US since this time.[13] This debate was certainly stimulated by the publication of research conducted by the Sunshine Project in 2004, which evaluated IBCs based on several criteria that essentially revolved around public accountability. These criteria centred on how IBC reviews were recorded by institutions, and how accessible this information was to the public. They claimed that only 4% of the intuitions they contacted demonstrated adequate accountability (The Sunshine Project 2004, 4). They also identified over 30 companies with NIH funding, some of whom who were conducting biodefense research on 'select-agents' that had no NIH registered biosafety committee (The Sunshine Project 2004, 14). Since this time further criticisms of the IBC centric approach within the US have also emerged which have also focused on the absence of compliance within NIH funded institutions as well as the absence of voluntary application of these guidelines within the private sector (Race and Hammond 2008).

To sum up, the nexus between existing biosafety frameworks and dual-use governance remains a source of contestation within the US. This politicisation is undoubtedly important in making sense of emergent debates about responses to concerns about bioterrorism. This idea is subject to examination in later chapters.

Biosafety and the dual-use issue in the UK

In the UK, laboratory biosafety has been regulated since the emergence of concerns about recombinant DNA in the 1970s. Over time, the UK Health and Safety Executive (HSE) has become central to the oversight of research involving potentially dangerous pathogens and organisms, as well as laboratory and medical biosafety (Jasanoff 2005, 55; Nightingale and Mcleish in Lyall et al. 2009, 174). Health and safety measures, generally speaking, involve

[13] For a an introduction written at the time see Couzin (2004). See also a letter from 11 prominent members of the scientific community which discusses the weaknesses of IBCs (Cook-Deegan et al.. 2005). Another sceptical perspective on biosafety within institutions is provided in J.B. Tucker 2003. See also Klotz and Sylvester 2009, chap. 7 and Corneliussen 2006.

legal duties for employers, employees and contractors in the workplace. The primary legislation of biosafety in relation to genetically modified organisms, as well as biological agents, is the *Control of Substances Hazardous to Health Regulations of the Health and Safety at Work Act (1974*). This act created the HSE, which can design and implement secondary legislation in this area. The policy is in the main implemented through the Biological Agents Unit of the HSE, which also contributes to the development of secondary legislation. Following the terrorist attacks of 2001, the HSE has implemented new regulations. An advisory committee within the unit tasked with '*advising the Health and Safety Commission, the Health and Safety Executive, Health and Agriculture Ministers and their counterparts under devolution in Scotland, Wales and Northern Ireland, as required, on all aspects of hazards and risks to workers and others from exposure to pathogen's*[14] has also produced a series of annual reports and other publications, such as guidance for practitioners, which can be used to indicate the work and perspectives of the unit.[15]

The secondary legislation frameworks which are understood to be relevant to biosafety within the unit is the *Control of Substances Hazardous to Health Regulations (2002*), the *Genetically Modified Organism (contained Use) Regulations (2000*) as well as *The Management of Health and Safety at Work Regulations (1999*). The relationship between these regulatory frameworks in terms of the types of duties that they have created for employers, employees and contractors are outlined in the figure below

14 http://www.hse.gov.uk/aboutus/meetings/committees/acdp/ar2004.pdf.
15 http://www.hse.gov.uk/aboutus/meetings/committees/acdp/.

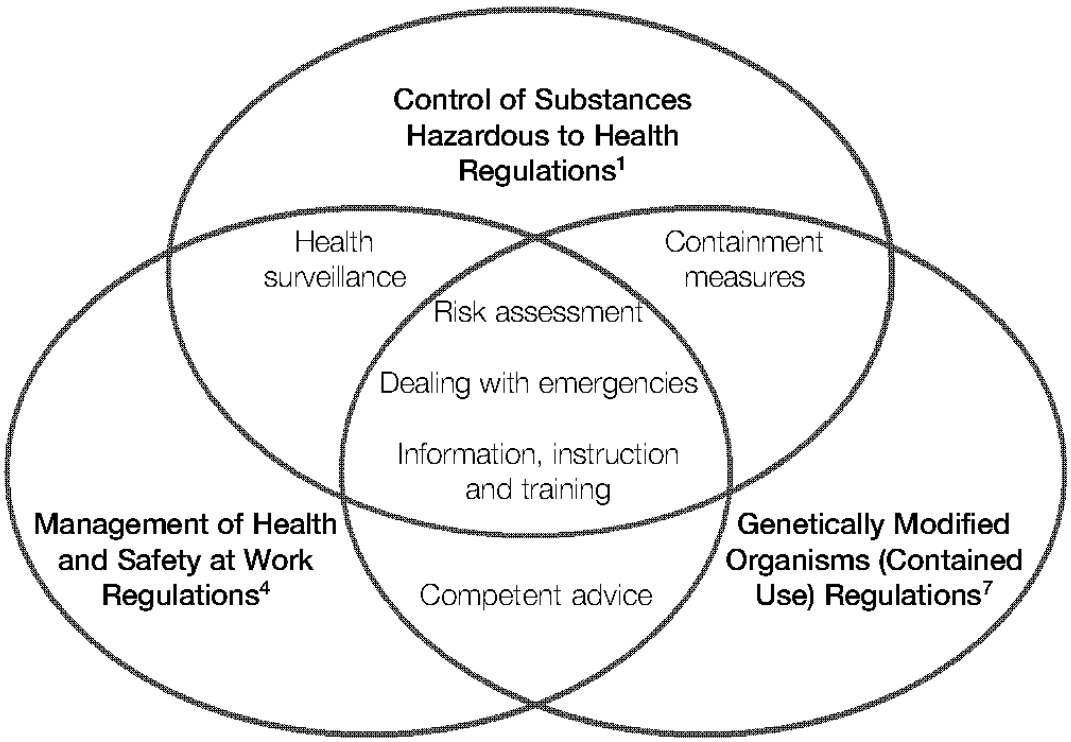


**Table 2 The relationships between UK health and safety regulatory frameworks**

*From:* Advisory Committee on Dangerous Pathogens (HSE) 2005

Nightingale and McLeish argue that in the main that UK legislators, have concentrated on tightening pre-existing health and safety practices and have not introduced any radically new requirements in response to concerns about the intentional misuse of biological agents and toxins (Nightingale and McLeish in Lyall et al. 2009). The HSE has identified publicly the Anti-terrorism, Crime and Security Act 2001 (ATCSA) as a relevant regulation to its work since at least 2006. However, since the terrorist attacks of 2001, there have not been substantive changes to the policies of the biological agents implementing unit within the UK (Corneliussen 2006). Neither have there been substantive changes to laboratory biosafety practices, including those involving research on dangerous pathogens (McLeish and Nightingale 2005; Nightingale and McLeish in Lyall et al. 2009). Since the emergence of concerns about bioterrorism, the biosafety system of the UK has received attention in relation

to the accidental escape of the foot and mouth disease virus from the high-level containment laboratory at Pirbright. This incident did provide an opportunity for reflection on anti-terrorism, as well as biosafety policies, in high-level biosecurity laboratories. Under the review that followed, however, it was found that the HSE was not required to take on further anti-terrorism roles in relation to biological agents (House of Commons, Innovation, Universities, Science and Skills Committee 2008, 16).

To sum up, dual-use concerns have not been understood to challenge the UK biosafety system. A key reason for this, is faith in the long established legally enforced controls on laboratories. These controls have also been understood, within the HSE as well as at parliamentary level, in the context of extra sets of checks and enforcement in relation to schedule 5 agents provided by the police force by the National Counter-Terrorism Security Office (NaCTSO) (House of Commons, Innovation, Universities, Science and Skills Committee 2008, 16). The impact of this on dual-use politics in a UK context is discussed further in later chapters and is contrasted with biosafety politics within the US.

### 2.4.3 Anti-terrorism Domain

Anti-terrorism policies in general terms are designed to prevent or mitigate the use and threat of violence by states and sub-state actors to coerce persuade and gain public attention. Concerns about bioterrorism were galvanised in the anti-terror domain and received increased public attention following the US Amerithax attacks of 2001, where the September 11th attacks in the US were shortly followed by the arrival of letters containing anthrax spores at five major US media offices. Several weeks later the offices of two US Senators were also targeted. Five people died, and at least sixty people were harmed. These events contributed to heightened anxiety in the US as well as in Europe about the threat posed by bioterrorism. Although the source of the anthrax spores was eventually identified as a US defence

laboratory, there have been concerns about the other means by which terrorists could access and use dangerous pathogens. Following these events the synthesis and even the modification of select-agents by terrorist groups are scenarios which have received both policy maker and public attention.

There is a long history of controls on scientific research and cutting-edge technologies within both the US and the UK. Since at least the Second World War, both states have sought to protect the advantage gained from military scientific progress. In the Cold War era, the vast majority of science and technology of military interest was developed in a military context. Security regimes have developed within leading states (and between allies) that utilised inward looking controls to prevent the leakage of military-related technology, scientific knowledge and expertise to their enemies. This primarily involved controls over exports, in addition to the screening and restriction of personnel access to classified technologies and associated scientific and information (Relyea 1994). Since the BTWC was signed into force in 1972, states have also been required under international law to prevent the production, development and stockpiling of biological weapons within their jurisdictions. This has tended to be enforced through the criminalisation of such activities.

Towards the end of the Cold War era many states became increasingly concerned about the threat posed by the international trade of chemical and biological agents and technologies that could contribute to prohibited state level or sub-state weapons programmes. This led to the emergence of the so-called ‘Australia group’, which is a voluntary, informal export-control arrangement between member states.

Increasing apprehension of the dual-use nature of simple and widely available biological techniques, materials and technologies, as well as the growing significance of international terrorism, has galvanised dual-use concerns. These concerns in turn have led to fears that

existing national regulation and international agreements can no longer be relied upon to prevent rogue states and particularly sub-state actors from developing terror weapons (Sims 2009; J.B. Tucker 2003; Kelle, Nixdorff, and Dando 2006). At international level this has led to the reassertion of states obligations under article IV[16] of the biological and toxin weapons convention in UN resolution 1540 which required states to establish domestic controls to *'prevent the proliferation of nuclear, chemical and biological weapons, and their means of delivery, including by establishing appropriate controls over related materials'*[17]

Concerns about the misuse of scientific research also resulted in the extension of the remit of the Australia group in 2002, who since this time has sought to control the spread of technology by '"intangible means", including via e-mail, phone, or fax'.[18]

Developments within the life sciences have been perceived to necessitate a turn away from traditional arms control approaches towards broader biosecurity policies. The table that follows outlines characteristics of biological pathogens which make traditional non-proliferation controls unsuitable.

[16] Article iv reads: Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

[17] Available at http://www.un.org/sc/1540/.

[18] See: http://www.armscontrol.org/factsheets/australiagroup.

| Fissile materials | Biological Pathogens |
|---|---|
| • Do not exist in nature | • Generally found in nature |
| • Non-living, synthetic | • Living, replicative |
| • Difficult and costly to produce | • Easy and cheap to produce |
| • Not diverse: plutonium and highly enriched uranium are the only fissile materials used in nuclear weapons | • Highly diverse: more than 20 pathogens are suitable for biological warfare |
| • Can be inventoried and tracked in a quantitative manner | • Because pathogens reproduce, inventory control is unreliable |
| • Can be detected at a distance from the emission of ionizing radiation | • Cannot be detected at a distance with available technologies |
| • Weapons-grade fissile materials are stored at a limited number of military nuclear sites | • Pathogens are present in many types of facilities and at multiple locations within a facility |
| • Few non-military applications (such as research reactors, thermo-electric generators, and production of radioisotopes) | • Many legitimate applications in biomedical research and the pharmaceutical/ biotechnology industry |

**Table 3 Contrasts between the characteristics of nuclear and biological weapons as a subject of oversight**
*From*: (J. B Tucker 2006)

National responses to the new threat of bioterrorism in the 21st century can be understood to have impacted upon the emergence and governance of dual-use issues in several ways at national level. Primarily this has involved increased legal controls upon select-agents. Paradoxically, however, concerns about bioterrorism have also led to calls for increased

engagement in research with agents and biological processes that have been of highest misuse concern, especially within the US (Tucker 2003), an issue discussed at greater depth in this thesis in relation to the public health domain. In the following section the nature of the US anti-terrorism domain, as well as its impact on dual-use governance, is discussed.

The anti-terrorism domain and the dual-use issue in the US

Within the US, government security controls over science and technology have generally been understood in the context of the requirement for the state to encourage the openness of science to the greatest extent possible. This is epitomised in the US context in the *Directive on Fundamental Research Exemption NSDD-189* (1985), which asserts that 'basic' research should be exempt from controls on dissemination to the fullest extent possible. In the US restrictions have primarily involved controls over exports and screening of personnel working in military research. This has also led to, at times, controls over research and technology developed outside a military context. Relyea (1994) highlights this oversight system involved censorship and suppression as well as invention secrecy. These were in the main implemented through a series of federal regulations under the *Atomic Energies Act of (1954*), which allows for the classification of state funded research.

During the Cold War period, the focus of US biological non-proliferation policy was on the prevention of states acquiring biological weapons of mass destruction. It wasn't until towards the end of the Cold War period that US attention turned to domestic terrorist threat. This is exemplified in the *Biological Weapons Anti-Terrorism Act* (1989). This act made it illegal for anyone (without good reason) to knowingly develop, produce, stockpile, transfer, acquire, retain, or possess any biological agent, toxin, or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so.

Seven years later, Congress passed the *Antiterrorism and Effective Death Penalty Act (1996)*, primarily in response to the 1984 Rajneeshee Salmonella bioterrorism incident as well as the failed Aum Shinrikyo anthrax attack in Kameido Japan. The Act expanded upon the 1989 Act in several ways, with a focus on ensuring terrorist threats and attempts were covered under the regulation. This Act also broadened provisions to explicitly include the use of recombinant DNA technologies in the synthesis of new of existing pathogens (Ferguson 1997). Under this Act, the legal basis for a select–agent regulatory framework was also established. The Centre for Disease Control (CDC), an organisation within the US DHS department, was charged with the development of a list of select-agents, as well as of regulations to prevent national and international terrorism (Ferguson 1997, 359).

Since 2001 several anti-terrorism Acts have impacted upon the oversight of select-agents. The first is the *USA Patriot Act (2001*), The Act impacted upon the program by criminalising the shipping, possession, and receipt of select-agents for restricted persons.[19] This Act also expanded on existing bio-weapons statute, explicitly criminalising the possession of select-agents without just cause (*USA Patriot Act of 2001*, sec. 817).

Under the *Bioterrorism and Preparedness Act 2002*, as well as the *Agricultural Bioterrorism Acts* of 2002, two institutions were charged with the development, maintenance and oversight of lists of select-agents. The first was the HHS (Department of Health and Human Services)

[19] Under the Patriot act restricted persons are understood to include any person who:
(A) is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;
(B) has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;
(C) is a fugitive from justice;
(D) is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));
(E) is an alien illegally or unlawfully in the United States;
(F) has been adjudicated as a mental defective or has been committed to any mental institution;
(G) is an alien (other than an alien lawfully admitted for permanent residence ) who is a national of Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, or any other country to which the Secretary of State, pursuant to applicable law, has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism;
(H) has been discharged from the Armed Services of the United States under dishonorable conditions.

which already had responsibilities under the *Antiterrorism and Effective Death Penalty Act* 1996 (sec. 511); the second was the Department of Agriculture (USDA). Under these acts, the HHS and USDA were also required to co-ordinate with each other.

Since this time the CDC within the HHS, as well as the Animal and Plant Health Inspection Service (APHIS), have developed three select-agent lists. The CDC is responsible for a list dealing with public health and the APHIS is responsible for two separate lists dealing with plants and animals. In essence, however, each of these lists is associated with a comparable set of legal requirements. Under these regulations, all entities possessing 'select-agents' are required to designate an individual who is responsible for ensuring safe research practices, storage, transport and reporting of loss, theft and accidents (See, for example, Hallie 2011). Since the implementation of the new select-agent rules, there has been sustained criticism of these regulations within the US. Many of these criticisms constitute attacks on the wisdom of controlling select-agents as a strategy to prevent misuse more generally (Rambhia, Ribner, and Gronvall 2011). Added to this there has been sustained concern within government and federal agencies that scientific research may have been negatively impacted upon unduly by the implementation of anti- terror regulations related to select-agents (Knezo 2002, 2). Prominent members of the scientific community also continue to express concerns publicly about the impact of controls on medical and biodefensive research (for example Franz et al. 2009). Such contentions have led to a series of institutional and academic investigations into the impact of US select-agent controls (Dias et al. 2010; Fischer 2006; Franz et al. 2009).

Another key issue area within this domain has been contestation over the suitability and effectiveness of scientific self-governance in relation to the threat of terrorist misuse of research. Following the Amerithrax attacks there were heightened concerns within aspects of the US executive that existing declassified information related to bio-weapons research, as

well as cutting-edge life science research, could be utilised by terrorists. Essentially, the responses to terrorism relevant to the practice of life science research were laid out in the *House of Representatives Resolution 514 (2002*). The resolution expressed concern about the publication of a piece of research that demonstrated how to construct the polio virus utilising commercially produced polynucleotide sequences. These concerns were expressed with reference to terrorist groups as well as states of proliferation concern. The resolution called for publishers and editors as well as the broader scientific community to develop ethical standards to ensure against the publication and dissemination of dangerous information. The resolution also called for the executive to conduct a review of statute and policy regarding the publication and classification of research in light of the recently emerged concerns.

Following the resolution, a joint editorial statement appeared in *Nature* which stated that its actions came in response to a meeting between scientific leaders, national security professionals and government aides (Atlas et al. 2003). The statement reminded readers of the 'active role' that key journals had taken so far in the development of responses to biosecurity concerns. It was also argued that the scientific community had dealt with such concerns with regard to nuclear technologies; thus they were well placed to lead discussions on this issue (Atlas et al. 2003). The statement affirmed the journal's responsibility to ensure the advancement of biodefense research. There was also an assertion of the author's commitment '*to dealing responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing our capacity to identify such issues as they arise*' (Atlas et al. 2003). This commitment also included the implementation of policies to review papers of dual-use concern, and where necessary modify, or censor publications. The actions of the scientific community have been characterised by some as pre-emptive attempts to stave off regulations. For example, Harris and Steinbruner of the

Harvard Sussex CBW programme stated that '*US scientific organizations moved quickly to minimize the possibility of government-mandated restrictions on fundamental research, offering governance by scientists themselves as an alternative'* (Harris and Steinbruner 2005, 2). Bearing in mind the political context just described, it is unsurprising that there have been a series of investigations into the dual-use review policies of biomedical Journals in the US and internationally since this time (Aken and Hunger 2009; Resnik, Barner, and Dinse 2011).

The most influential report produced on the issue of US dual-use research oversight remains '*Biotechnology research in an age of terrorism'* (National Research Council 2004). This document advocated the extension of existing scientific self-governance and biosafety practices in the context of existing national regulations. The report also called for the establishment of the National Scientific Advisory Board for Biosecurity (NSABB), a board which is primarily tasked with providing guidance to the US government on dual-use issues. The subsequent work of this board is subject to in-depth examination in chapter 5.

To sum up, on the surface level developments within the US anti-terrorism domain have appeared sporadic, and often been characterised as involving vocal aspects of the scientific community resisting government intervention. However, such a characterisation neglects the fact that, at a national and international level, leading scientists and scientific institutions have contributed to a number of initiatives aimed at improving the understanding and governance of dual-use issues. So far within the academic literature, the specific impacts of this political environment on the emergence of dual-use governance in relation emerging fields of science and technology remain unclear and contested. This in part stems from the vested interest the broader scientific community is understood to have in relation to dual-use issues. These observations inform analysis in later chapters.

<u>The anti-terrorism domain and dual-use issues in the UK</u>

In the UK, there have been no major changes in scientific practice resulting from dual-use concerns aside from increased controls over select-agents, as discussed within this chapter with regard to the biosafety domain. The primary response to concerns about the misuse of scientific research in the UK in the period 2001-2003 was the development of an ethical code of conduct for the scientific community, by the scientific community. This had broad support from the Home Office, the British Foreign and Commonwealth Office (House of Commons Foreign Affairs Committee: 2003), funding councils and learned societies. There were also initiatives being developed by academics which have been discussed at international level since the 2nd BTWC inter-sessional process (Rappert 2009). It was emphasised by Pearson at the time that in order to be effective, such codes would need to draw upon current regulations and also be embedded in existing governance frameworks, such as those directed at health and safety and the BTWC (Pearson 2004). However, even from this early period, some cynicism was expressed in relation to the value and motivation of scientific codes. For example, a 2004 report on a meeting co-organised by the Royal Society and Welcome Trust stated that

> 'although some scepticism was expressed about the value of codes of conduct, it was suggested that the scientific community should take the lead in determining any codes of conduct or good practice, to pre-empt their introduction through legislation or other 'top down' approaches' (Royal Society and Wellcome Trust 2004, 1).

The Royal Society and Wellcome Trust also supported other forms of self-governance as early as 2004, usually with an explicit preference for this approach over legislation. Another approach identified was the extension of research funding review procedures. However it was unclear at the time how potential dual-use research could actually be identified in the absence of a risk assessment framework (Royal Society and Wellcome Trust 2004, 1). Another approach discussed in 2004 was the restriction of the communication of research results, but it was made clear that '*the very strongly and widely held belief was expressed that preventing*

*publication of basic research would not prevent its misuse*' (Royal Society and Wellcome Trust 2004, 3). There were also a series of arguments provided against censorship. The first argument related to the practical unfeasibility of censorship. This included the idea that censored scientific information could be communicated via other formal and informal routes (including email, conferences and publication in alternative journals or on websites). The second argument was that research which was censored was likely to be conducted by other researchers '*within two years*' anyway (Royal Society and Wellcome Trust 2004, 3). The third argument related to the impact which censorship could have on the development of science and technology. Specifically, it was argued that the open publication of research was essential to knowledge exchange, as well as to the peer review process. The final argument related to accidental findings; it was stated that the publication of accidental 'dual-use' results (such as the now notorious mouse-pox experiment) would make other scientists aware of potential unintended results (Royal Society and Wellcome Trust 2004, 3–4).

Following the publication of the US National Academies of Science's (NAS) '*Biotechnology Research in an Age of Terrorism'* report in 2004, the Biotechnology and Biological Sciences Research Council (BBRSC), Medical Research Council (MRC) and Wellcome Trust began to implement policy changes directed against the risk of misuse. Such activities were described in a joint BBSRC, MRC, Wellcome Trust publication and included

> [the] introduction of a question on application forms asking applicants to consider risks of misuse associated with their proposal; [the] explicit mention of risks of misuse in guidance to referees as an issue to consider; [the] development of clear guidance for funding committees on this issue and the process for assessing cases where concerns have been raised; [and the] modification of organisational guidelines on good practice in research to include specific reference to risks of misuse (BBSRC, MRC and Wellcome Trust 2005).

Despite explicit reference to dual-use issues and the NAS report in guidance to those involved in funding application processes at the MRC, Wellcome Trust and BBRSC, there remains no publicly available evidence that any research applications have been modified as

a result of dual-use concerns within the UK. Indeed, in the context of an earlier statement (2004) made by the Wellcome Trust and the BBRSC, it is unclear how dual-use work could be identified and what action could actually be taken if there had been dual-use concern. In response to the perceived absence of awareness and understanding within the scientific community, a key area of activity within the UK has been awareness-raising among scientists. However, research conducted as part of a the Wellcome funded '*Building A Sustainable Capacity for dual-use bioethics*', as well as other projects associated with the Universities of Exeter and Bradford, have highlighted that educational activities have tended to be limited in nature, with dual-use issues only beginning to enter a limited number of ethics courses provided for scientists.[20]

To sum up, in response to concerns about bioterrorism, the UK government tightened up laboratory biosafety and biosecurity; however, since this time public and press attention in relation to the issue has been minimal. UK scientific institutions, motivated primarily by concerns about bioterrorism in the early 2000s, have implemented some dual-use policy. However, these activities have had very little impact on the actual practice of scientific research so far. Key activities in this area have been small initiatives, primarily conducted by academic researchers, designed to have impacts at a more local level and in relation to specific fields. This suggests that the domain has a minimal impact on the governance of the majority of new and emerging fields of science and technology within the UK. These themes are taken up in analysis in later chapters.

### 2.4.4 The Public Health Domain

The term public health essentially refers to, '*the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of*

[20] http://www.brad.ac.uk/bioethics/Monographs/.

*society, organizations, public and private, communities and individuals'* (Winslow 1920). The state tends to take a leading role in the field of public health provision within liberal democratic states; however, many activities may also be conducted in partnership with the private sector. The primary functions of public health systems are disease surveillance and intervention, which require having complex and risk-specific systems in place. Increasingly, public health theory, practice and capabilities are considered important in responding to the risk of biological attack, and are related to increased concerns internationally about the threat of infectious diseases, regardless of origin (Kelle 2007; Aldis 2008; Fidler and Gostin 2008). A term often utilised to describe this area of governance in the US and EU is 'Bio-preparedness'. In its broadest sense, this term can be used to define all activities within states which are understood to improve the ability of governments and responsible organisations (such as Public Health institutions) to predict, prevent and respond to biological based incidents. This also includes activities directed at the attribution of responsibility for bioterror attacks (Lentzos and Rose 2009). In order to provide a boundary to my own understanding of this area of governance within this thesis, the term 'public health domain' is used to denote the role of public health thinking, institutions and resources in dual-use governance. This includes bio-defensive research capacity.

The Public Health domain and the dual-use issue in the US

In the US since at least the early 1990s, the dual-use issue has been placed in the context of long-standing concerns within aspects of the US government about the threat posed by bioterrorism (Wright 2006; Reppy 2006; 2008; Kelle 2007). Such concerns, supplemented by growing concerns about natural infectious disease, have led to the growth of public health and security infrastructures directed at the threat of bioterrorism and naturally occurring infectious diseases. In 2004, for example, four pillars of US 'biodefense' were identified:

- *Threat Awareness, which includes biological weapons-related intelligence, vulnerability Assessments, and anticipation of future threats.*
- *Prevention and Protection, which includes interdiction and critical infrastructure protection.*
- *Surveillance and Detection, which includes attack warning and attribution.*
- *Response and Recovery, which includes response planning, mass casualty care, risk Communication, medical countermeasures, and decontamination.*

(The White House, Office of the Press Secretary 2004)

Within the US context there has been a sustained discussion of the consequences of the policy collision that occurred between national security and public health within both academic and policy literature in the period following 2001. The speed at which events unfolded following the 2001 attacks undoubtedly contributed to the intense politicization of this issue within the public health domain. This politicization led to debates about the skewing of institutional and funding priorities, particularly in regard to the Bio-shield programmes which involved large investment into a failed small-pox vaccination programme (Fidler and Gostin 2008, 101).

Another development relevant to the dual-use issue is the expansion of US bio-defence research, including work on select-agents pathogens.[21] This has led to a vastly increased number of high level containment facilities, and considerably increased the number of individuals working with select-agent pathogens. Bearing in mind the disordered and un-legislated nature of biosafety governance structures within the US, it is unsurprising that this issue has led to concerns domestically. It has also created an imperative and mechanism for the identification of dual-use threats, with defence laboratories as well as private companies[22] actively assessing published work for dual-use potential, as well as the feasibility of the misuse of this information by terrorists.

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21 Most notably the National Biodefense Analysis and Countermeasures Centre.

22 The author interviewed a researcher at one of these companies involved in assessing the dual-use threat posed by civilian research, who wished to remain anonymous, and who would not reveal details of the federal contract this work was conducted under.

This practice has not been without criticism domestically for two primary reasons. The first is the absence of a convincing means of risk assessment; for example, Carus and Petro argue that it may be necessary to undertake research to address threats validated by US Intelligence (Petro and Carus 2005). However, others have been more sceptical of the reliance on the intelligence community with regard to bio-weapon capabilities. Leitenberg (2005, 88) and Vogel (2008b) have argued that US Intelligence has tended to overestimate the bio-weapon capabilities of enemies, and that it has done so with regard to the current bio-terror threats. This suggests that any risk/benefit analysis of biodefense research at federal level may be skewed by worst-case and inaccurate bioterror threat assessments. The second cause for concern has been the risks associated with such research, including local concerns about laboratory accidents (Klotz and Sylvester 2009) and the risk of the leakage of technology and know-how from biodefense laboratories into the hands of state enemies terrorists (Tucker 2006). There also have been numerous criticisms of the US pursuit of threat characterisation research, which involves the creation of bioweapons in order to test defensive measures without transparency and convincing international oversight (Bansak 2011; Klotz and Sylvester 2009; Steinbruner et al. 2005).

The impact of these discourses on the governance of specific emerging science and technologies remains unclear within the existing literature. However, this situation certainly suggests an increased institutional capacity for the identification of dual-use aspects of biotechnology within this domain, as well as the possibility of political contention over the appropriate response to such concerns.

Such tensions have emerged from the very real conflicts that exist between homeland security and public health communities. As Fidler and Gostin have highlighted, traditionalists within the public health and security realms have resisted weaving these previously separate realms

together. Much of this conflict has revolved around the role and governance of the biosciences in response to the threat posed by pathogens (Fidler and Gostin 2008, 2). The concerns of non-proliferation experts have also been prominent within this domain.

To sum up, in the public health sector political disagreements over threat characterisation research and military investment into the biosciences in response to bioterror threats have informed discussions about the dual-use issue in the US. In later analysis the specific impacts that these debates have had on the governance of new and emerging science and technology are examined.

The Public Health domain and dual-use issues in the UK

Within the UK, Lentzos and Rose (2009) have identified several institutions which are central to the state's capacity to predict, prevent and mitigate the threat of bioterrorism in the public health domain. The primary institution is the Civil Contingencies Secretariat (CCS), which sits within the Cabinet Office and works in partnership with government departments as well as key stakeholders to enhance the UK's ability to prepare for, respond to and recover from emergencies.[23] The Health Protection Agency is another institution with a mandate related to the threat posed by infectious disease. In addition, more than thirty other state, quasi-state and non-state bodies were also identified by Lentzos and Rose as having responsibilities in this domain. The primary role of these institutions in the UK context appears to be galvanising existing health surveillance and emergency response infra-structures in order for them to deal with bio-attack scenarios. As Lentzos and Rose state, the UK approach to bio-threat management, whatever its source, is one of 'resilience' (2009, 245).

[23] http://www.cabinetoffice.gov.uk/content/civil-contingencies-secretariat.

In the UK context there has been little vocal disagreement between organisations within the public health domain about bioterror response policies between institutions, although dissent directed at regulatory burden is common within the scientific community. The lack of bio-defence research imperative within the UK has also meant that, in contrast to the US, little energy has been directed towards identifying and responding to misuse concerns surrounding 'grey-area' bio-defence research by academics and policy makers. The current focus on preparedness, especially within the UK, has also contributed to a situation where there is less attention paid to science and technology developments in domestic policy formation, as policy is focused more heavily on responding to the misuse of research rather than attempting to identify specific research that could be misused, or justifying investment into technical responses to the issue.

### 2.5 Synthesising Domains: Dual-Use Risk Pre-Assessment Regimes

So far in this chapter, a broad collection of largely independent governance activities at national level have been introduced under the label of dual-use governance. This chapter has also provided a broader ideational and histo-political context of these activities, which has led to the identification of four domains of dual-use governance. It has been demonstrated that the dual-use issue been constructed as a series of largely discreet challenges by stakeholders in each of these domains.

In both the US and the UK there are institutional overlaps between the domains identified, for example, scientific institutions have played a role in many of the domains as a source of expertise or as a target for governance activities. There is also likely to have been flows of ideas and knowledge between the domains via the various international policy shaping

networks that have developed in the previous decade.[24] So far, however, care has been taken within this chapter not to imply that there exists an overall single 'project' or 'rationale' which unites each of the governance activities identified. This is because an essential step in understanding the governance of dual-use issues is to appreciate that, while most policy makers in this field would agree that dual-use governance to some extent incorporates each of the activities identified above, there have not necessarily been self-aware national projects to define overall goals or develop the political and institutional capacity to reach them. This means that care must be taken not overestimate the extent to which such responses are integrated as part of a broader governance scheme. Such assumptions are tempting considering the prominence of holistic governance discussions within the literature. For example, the 'web of prevention' concept came to prominence as early as 2004 in an International Committee of the Red Cross (ICRC) statement which defined the project of preventing the hostile use of the life sciences as involving '*a range of synergistic measures'*, meaning that dual-use governance was '*by necessity a multidisciplinary endeavour*' (ICRC 2004). The 'web of prevention' concept has since been used in several ways in academic literature, and it is worth briefly distinguishing these in order to demonstrate how the concept is utilised within this thesis.

The concept can be utilised in two central ways in academic analysis. First, it may be utilised to denote the scope and consequences of a cumulative set of practices, as well as the means by which actors have co-operated within a conceived regime. This then enables discussion of the nature and prospect of an overall regime. The second use of the web concept is as part of

[24] These networks have developed as a result of institutional governance activities associated with learned societies and non-governmental organisations such as the Centre for Scientific Culture Alessandro Volta network, the BTWC (especially in relation to review conference and inter-sessional processes), academic projects such as the Wellcome funded Dual-use Bioethics Project, US government departments such as the US department of HHS, the NSABB meetings and report consultation process, and a series of ELSI and bio-security activities related to the field of Synthetic biology, including notably the S.Bx series of events.

the development of a 'gold standard' for dual-use governance regimes, against which the 'strengths' and 'weaknesses' of existing governance can be evaluated.

Within this thesis the concept of the governance web is utilised in the first, non-normative sense, as a key conceptual step in delineating the practices and politics of existing governance frameworks in the UK and the US. It has already been demonstrated in this chapter that the US and the UK exhibit some variation in how dual-use issues have been addressed in the domains identified. However, before it is possible to compare these '*styles*' of dual-use governance, it is necessary to de-limit the extent of these governance frameworks and to be more explicit in the criteria by which they are compared.[25]

The risk governance literature provides some useful concepts for characterising dual-use governance styles in national contexts. In the following section I draw upon several scholars associated with the International Risk Governance Council (IRGC), a non-governmental organisation founded in 1999, in order to '*bridge the increasing gaps between science, technological development, decision-makers and the public*'.[26] While the academic literature associated with this organisation is tightly bound with conceptions of what 'good' risk governance should look like, it also provides a series of analytical heuristics, firmly grounded in existing institutional approaches to risks in developed nations which can act as a departure point for the discussion and analysis of dual-use governance activities.

The first concept of interest is that of 'systemic risk governance'. This can be defined in contrast to 'simple' risk problems, which generally involve the unquestioned application of pre-defined institutional decision-making routines to risk problems as they manifest, utilising existing standards and decision-making processes. In comparison, systemic risk governance

[25] In effect, addressing this issue ensures that I am explicit about how I conceptualise the 'phenomenon of interest'(George and Bennett 2005) within this study.

[26] Further information available at http://www.irgc.org/.

problems are characterised by complexity, uncertainty and ambiguity (Renn 2008; Renn, Klinke, and Asselt 2011; Klinke and Renn 2006). These issues are complex, as they do not involve simple causal chains of events with easily quantifiable consequences, but rather a large set of intervening variables. These issues are uncertain, as there is insufficient data or information to convincingly assess the probability and outcomes of bad events. They are also ambiguous, as they typically include conflicts over values, such as different stakeholders taking contrasting 'legitimate' standpoints on a given issue (Renn, Klinke, and Asselt 2011, 235). Different aspects of the dual-use issue can be conceptualised as 'systemic risks'. To give some examples, the risks posed by terrorist scenarios are complex because of the number of variables in threat assessment, with regard to the technology as well as to the intentions and capabilities of actors. There is also an absence of criteria for measuring the probability and effects of misuse of research and technology by terrorists groups, meaning discussions are largely based on analogy. Finally, there is ambiguity with regard to how the values of 'scientific freedom' and 'security' should be conceptualised and balanced.[27] The concept of 'systemic risk governance' is further unpacked below, and some categories of risk governance behaviour, relevant to describing dual-use governance activities, are introduced.

Systemic risk governance involves multi-stage processes directed at the identification, communication and evaluation of risks. Of particular interest within this thesis are the activities which occur during what is known within risk governance literature as the 'pre-assessment' phase. The term 'pre-assessment' refers to the normal political process by which novel issues (i.e. risks/threats) tend to be identified and constructed as governable problems within modern societies. The pre-assessment phase is of most interest within this thesis, as it

[27] Despite that fact that all stakeholders within dual-use governance may not have conceived of the dual-use issue as a 'systemic' rather than 'simple' risk issue, it still makes sense to conceptualise dual-use governance more broadly as systemic risk governance, as this concept includes the type of activities seen within the governance of simple risk issues.

describes the type of activities that have been discussed or have already been implemented in the relatively short time period that dual-use techno-sciences have been on the agenda. This phase is also most important in identifying and framing dual-use issues, and therefore most revealing in relation to the ideational, discursive and histo-political factors that give shape to dual-use governance. Renn has identified four interrelated components that would be expected in the pre-assessment stage or in an emerging systemic risk regime (Renn 2008, 48–52). The first component is the framing of the problem, which often involves disagreements over problem definition (such as the scope, severity, causation). The second component involves systematic searches for new hazards, which may, for example, see an institution being tasked with an in-depth systematic enquiry into the area in order to identify the extent and source of risks. The third component is to identify existing systems or risk governance already in place within relevant institutions to identify and respond to the problem in hand. The final component is the selection of scientific criteria for risk assessment in which involves the adoption of key assumptions, conventions an procedural rules for assessing risks (Renn 2008, 49) and may involve the development of initial plans for the 'roll-out' of these conventions across relevant institutions. Within the analysis which follows, the extent to which these types of activities are taking place as part of an overall national approach to the governance of dual-use issues will be examined.

### 2.6 Conclusions

In this chapter, two central lines of argument have been developed. The first relates to the range of responses to dual-use issues which have emerged within the four domains of governance identified within the US and the UK. Each of these domains provided a distinct political context for dual-use governance initiatives which emerged primarily in the period between 2003 and 2006. However, existing literature has not traced the effects of the politics

and practices within each of these domains on the governance of specific biotechnology fields of dual-use concern. It is clear that this requires further investigation in order to develop a clearer understanding of the practice and broader political context of dual-use governance at national level. Second, discussion of the concept of overarching models of national responses to dual-use issues, such as 'governance webs' and specific 'risk-reassessment regimes', has so far suggested an absence of agreed overarching political and scientific rationale to bring to bear on dual-use issues. This means that the current situation within a national context is best understood as a patch-work of relatively discreet governance activities (Kelle 2012b). A key question which emerges as a result of this conceptualisation of the political landscape is the extent to which there have been political attempts to overcome the challenges raised by dual-use as a complex risk issue within national contexts. Such actions, by necessity, involve attempts to transform norms within domains, as well as to alter relationships between these domains with regard to the dual-use issue. This is in addition to questions about how various domains have generated policy initiatives, and impacted upon the implementation of these initiatives.

In the following chapter an analytical framework is developed which allows for these lines of enquiry to be further developed. In particular, this involves paving the way to examine the scope, politics and practice of dual-use governance within the UK and the US.

# Chapter Three: Theory and Methods

## 3.1 Overview and Introduction

This chapter begins by arguing that the concept of 'security' is a suitable departure point for the study of dual-use governance. This claim is based on trends as well as gaps within existing academic and policy literature which addresses the dual-use issue. Following this, the sub-field of securitization theory is introduced as an appropriate field to provide a basis for an analytical framework for the study of the emergence of dual-use governance. This is followed by the development of an analytical framework for the study of the emergence and practice of dual-use governance which is tailored to the requirements of a comparative case study. It is also argued that certain concepts utilised within this study are of value to other constructivist scholars who utilise securitization theory. Finally, the research design and methodologies adopted in this thesis are discussed.

In the context of the overall thesis, this chapter is intended to outline how an analytical framework has been developed in order to refine and address the central research question, which specifically relates to:

- the *subject and scope of dual-use governance*
- the *politics and practice of dual-use governance*
- the *nature* and *prospect* of national approaches to dual-use governance.

### 3.1.1 Dual-Use, Security and Academic Research

References to 'security' are rife within the dual-use governance literature; this is not at all surprising considering the nature of the issue under discussion, as well as the political context in which the issue emerged. What is interesting however, is the different roles that ideas related to security have played within existing academic research. Through briefly exploring these roles, this section provides an account and justification for the approach adopted within

this thesis. Within this approach a specific analytical conception of security becomes the focus of a comparative analysis of dual-use governance within the US and the UK.

Within academic studies of dual-use issues, conceptions of 'security' have played a fundamental role in the emergence, design and analysis of enquiry. First, academics have studied security as a 'value' which, does or should, impact upon decisions about dual-use issues. This is most apparent in the work of ethicists who have looked at this area (Miller and Selgelid 2007). A second way in which academics have studied this area is to focus on the transformations of scientific practices and innovation policy in the name of security(Rabinow and Bennett 2012). Third, academics have sort to develop a clear conceptualisation of security as an ends in relation to dual-use issues. This has included work how to approach the dual-use issue from a risk-assessment perspective (Tucker 2012), or work which outlines more holistic approaches to conceptualising the overall project of dual-use governance (Rappert and McLeish 2007). A final type of work, however, has sort to emphasise the contingency in way in which dual-use issues can become (or fail to become) conceived as security threats. As well as the nature of contemporary security practices in given contexts, and how these help co-produce dual-use concerns (Rappert 2007). Each of these areas has impacted upon the development of research within this thesis. However, there are some key ideas and observations within this literature which have been fundamental to how I understand and have chosen to study the politics of security which surround dual-use issues.

The first, is that dual-use governance has commonly been understood to involve an institutional, ideational and co-operational 'overlap' between formally distinct areas of governance (McLeish and Nightingale 2007; Fidler and Gostin 2008). However, the nature and extent of the overlap at policy level does not appear to be uniform within the US and Europe, despite the fact that many academics have claimed that there were comparable levels

of concern expressed about bioterrorism in both Europe and the US in the 5-7 year period that directly followed the terrorist attacks of September 11th (Rees and Aldrich 2005; Lentzos 2006; Meyer 2009). This suggests that it is not possible to simply explain away the question of why dual-use governance is different in the UK and the US with reference to subjective levels of fear of bio-terror attack experienced within key institutions in Europe and the US.

The contrast between US and European approaches to bioterrorism in particular has attracted interest from scholars in the field, and certainly does not appear straightforward (Lentzos 2006). Instead, there are an innumerable range of ideational, institutional and historical factors which could be understood to impact upon the phenomena of dual-use governance within the UK and the US. In the context of this thesis, there is a requirement to identify and examine some important and specific aspects which can help in conceptualising the practice and politics of dual-use governance. A focus on the politics of security is an obvious approach, particularly when one bears in mind that comparisons made between US and European approaches by policy practitioners and commentators are usually implicitly or explicitly along a non-security/ security axis.[28] Despite this, little attention has been paid to the political process by which the principles of dual-use governance have been developed and institutionalised in relation security discourses, institutions and practices- as well as the effects this has in relation to specific dual-use issues. Such thinking, leads to questions about who can make issues subject to security governance, the nature of such political processes, as well as the ideational aspects prevalent in the governance of dual-use issues as a security

[28] For example, in relation to proliferation risks associated synthetic biology, a classified report from the Ottawa embassy in response to an Australia group meeting highlights the view that 'US and EU approaches represented two ends of the scale' (C O N F I D E N T I A L SECTION 01 OF 02 OTTAWA 000716 SIPDIS STATE FOR ISN/CB (ASOUZA) E.O. 12958: DECL: 09/14/2019 TAGS: PARM [Arms Controls and Disarmament], PREL [External Political Relations], ETTC [Trade and Technology Controls], CA [Canada] SUBJECT: CANADA: RESPONSE TO AUSTRALIA GROUP). NON-PAPERS REF: A. STATE 087595 B. STATE 087596 C. STATE 087597 D. STATE 088010 available at http://dazzlepod.com/cable/09OTTAWA716/?rss=1.

challenge. In the following sections there is an introduction to how the field of security studies can potentially provide insights into this issue area.

### 2.2 The Concept of Security and the Fractured Field of Security Studies

The term 'security' refers to a region of human experience and behaviour which is political and fluid; it is unsurprising then that the meaning of term is essentially contested. Within the academic field of security studies, there are a number of divergent conceptualisations of the definition of security, as well as divergent approaches to its study. The table below, for example, outlines some key approaches and indicates some fundamental distinctions between major contemporary approaches to the study of international security:

| | **Referent Object** | **Views of Power** | **View of Truth** | **Main research focus** |
|---|---|---|---|---|
| Realism | States | Material | Objective | Power-balancing |
| Liberalism | Social Groups | Varies | Objective | Learning/ Institutions |
| Marxism | Economic Classes | Material | 0bjective | Capitalist problems, Socialist alternatives |
| Social Constructivism | Social Structure, Human Agents | Socially Constructed | Subjective | Reproduction of social order |
| Critical Theory | Humans and the earth | Varies | Subjective | Emancipation of all humans from harm |
| Feminist Theory | Gender | Masculinist vs. Feminist | Subjective | Gender relationships |

**Table 4 A comparison of the major approaches within international relations theory**
Adapted from (Smith 2010, 32)

The historical route that the field of security studies has taken in its development has shaped epistemic and ontological debates within the field. These developments stem from the changing practices in military security, the widening 'scope' of security studies in academia, the development of theoretical trends within IR and socio-political theories more generally (Baldwin 1997; Buzan and Hansen 2009). The debates between the various perspectives on the study of security have encouraged analysts to define themselves explicitly in relation to existing intellectual divides within the field. These long-standing discussions have also impacted upon the framing of debates within sub-fields of security studies.

Balzacq states that while '*in the abstract such [ontological and epistemic] discussions might be justified, they are often distracting at the empirical level'* (Balzacq 2009, 57). With this is mind, discipline-specific debates are addressed throughout this chapter in order to clarify the approach adopted. The intention, however, is certainly not to supplement '*the cottage industry'* (Baldwin 2001, 7) of redefining the concept of 'security' in terms of long-standing debates within or between branches of security studies**.** Instead, the aim is to develop and apply an analytical framework to the problem in hand in a replicable manner, which is drawn predominantly from a sub-field of security studies. This being said, it is also hoped that analytical tools developed within this work may be described in such a way that they might be useful to other scholars working within the security studies sub-field this work focuses upon.

### 3.2 An Introduction to Securitization Theory

Securitization theory, which has become established as a sub-field within security studies in the past decade, is well placed to address the question of the relationship between the concepts of dual-use governance and security. First, the sub-field focuses on the political

processes by which issues do or do not end up being governed as security issues, as well as the nature and consequences of security governance. As Buzan et al. (1998, 32) state,

> *[the field of] securitization studies aims to gain an increasingly precise understanding of who securitizes, on what issue, for whom, why, with what results and, not least, under what conditions.*

Second, there has been rich theoretical and increasingly methodological discussion within this sub-field (McDonald 2008; Balzacq and Burgess 2010). This has generated a valuable source of practical insights, as well as conceptual tools, relating to the issue at hand.

It is worth noting, however, that such pragmatism has raised its own challenges in the context of the study of security. In more traditional approaches to the study of international security, scholars have studied object threats to states, such as the military capacities of enemies, which were usually other states. However, increasing constructivist approaches have emerged which focus on the way in which such threats are constructed by actors (Smith 1999). This reframing of security threats, however, has also been associated with the study of a wider range of issues. As a consequence, the self-evidence of the scope of security studies has been brought into question. Such developments have also cast doubt over the ability of security scholars to continue to contribute constructively to understandings of security politics and practice.

The publication of *Security: A new framework to analysis* in 1998 reflected the growing dominance of a new approach to security studies. Within this approach greater emphasis was placed on the processes though which security challenges were identified and responded to. In particular this approach reflected an articulation of a research agenda which focused on the means by which issues are lifted above the democratic norms of politics, allowing actors to do something they would not be able to do under 'normal' circumstances.

Essentially, within predominant understanding of securitization, a *securitizing actor* identifies an existent threat to a *referent object* that requires some (usually urgent or somehow unprecedented) response. This is known as a s*ecuritizing move*. Securitizing moves are said to be successful when strategic *audience(s)* accept that the threat is in existence and requires a response advocated by the securitizing actor. This success is understood to be dependent on the qualities of the securitization move (i.e. rhetorical qualities of a communication which identifies a threat), as well as socio-historical factors *(facilitating conditions)* (Buzan, Wæver, and Wilde 1998, chap. 2).

The aim of all self-proclaimed securitization research fits within the broad remit of the field to answer the question of '*who securitizes, on what issues for whom, why, with what results and, not least, under what conditions*'.[29] There has also been general consensus on the terminology used; however, it is widely agreed among those who have reviewed the securitization literature that certain vagaries in key concepts within early descriptions of the theory have provided for a rather diverse set of interpretations and applications (Balzacq and Burgess 2010). This certainly rings alarm bells for those who would seek to establish an underlying intellectual rationale for the field of securitization studies, an issue which is addressed in depth later in this chapter. However, in the context of the more pragmatic approach adopted within this thesis, such debates have also highlighted the necessity for analysts to be clear about how they utilise securitization theory in their research designs and to be more explicit about how key analytical concepts are defined, as well as how they foresee their work contributing to securitization theory development and application.

### 3.3 Developing Securitization Theory in and for Analytical Eclectic Studies

[29] This does not account for critical school readings of securitization theory, which often seem to 'talk past' these aims and ask questions related to whether actors 'should' have securitized in given situations, for example Floyd 2007.

Even though an analytically eclectic approach (Sil and Katzenstein 2010) is adopted within this study, I argue that the conceptual tools developed here may be useful to the various types of constructivist scholars working with securitization theory. The term analytically eclectic is used here to refer to research which can be characterised as involving:

> (a) Open-ended problem formulation encompassing complexity of phenomena, not intended to fill gaps in paradigm-bound scholarship.
>
> (b) Middle-range causal account[s] incorporating complex interactions among multiple mechanisms and logics drawn from more than one paradigm.
>
> (c) Findings and arguments that pragmatically engage both academic debates and practical dilemmas of policymakers/practitioners.
>
> (Sil and Katzenstein 2010, 19)

In relation to point (a), this research is not meant to constitute an attempt to solve problems within existing research paradigms. Instead, the iterative process of engaging with policy and academic literature on this dual-use issue has led to the identification of concepts and theories developed by academics which are of use in developing a clearer conceptualisation of the broader political context of dual-use issues. An important device in this process is the development of middle range causal counts (b) which may contribute to more generalizable findings about the issue area. Such understandings are important for academics and policy makers in thinking about the emergence of dual-use concerns, as well as the feasibility of political responses to such concerns.

This being said, as Sil and Katzenstein (2010, 43) make clear, it is still completely feasible for researchers to engage in analytically eclectic research while still identifying strongly with a specific research paradigm (such as constructivism). For example, it can make sense to utilize consistent terminology drawn from a single paradigm when communicating some

aspects of the research method and design. This is particularly the case if researchers have a specific research community in mind (beyond the policy issue area they are studying) when presenting theoretical and methodological aspects of their research. For example, such practice is already common within contemporary security studies research where scholars attempt to speak to broader theoretical and methodological themes. A good recent example of this is Galbreath and McEvoy (2012). Such work is of course important in helping to maintain the link between needs of policy makers and academic research (Sil and Katzenstein 2010, 1).

In the case of this research, it is hoped that aspects of it will be of interest to constructivist security scholars without an immediate stake in the dual-use issue area. The term 'constructivist' is used here with reference to 'mainstream', 'positivist' constructivism (Wendt 1999, 39–40) – this includes scholars who may sit on either side of the agency/structure debate when it comes to designing research, or who emphasise the role of language in the study of security (Fierke and Jørgensen 2001). Uniting these scholars is an epistemological commitment to scientific principles in the design and practice of research. This is in contrast to post-positivist scholars, including post-structuralists, who reject scientific conceptions of theory and theory development, such as hypothesis testing, the centrality of causality in explanation and comparative case study research design, within social research. Be that as it may, there is no reason for positivist scholars to neglect the interesting lines of enquiry that post-structuralists have often taken up (Wendt 1999, 40). With this in mind, my work on securitization theory draws upon post-structuralist securitization research, and involves the examination of discourse and discourse production,

an issue that has traditionally been neglected by positivist scholars. However, I do not engage in the development of securitization theory for post-structuralist scholars within the field.[30]

My understanding of what constitutes 'good theory' reflects my rejection of the post-structuralist epistemology, and within this work the importance of the concepts of *accuracy, falsifiability, explanatory power, progressivity, consistency and parsimony'* (Vasquez 1995, 230), which are widely valued scholarly conventions, are apparent in the way in which I develop my own analytical framework and carry out research. While I do not necessarily believe that these constructs help us get at a true picture of social reality 'out-there', I certainly follow the more 'pragmatic'[31] line of reasoning that these scientific philosophical principles are (and indeed should be) important means to formulating and evaluating theory within the social sciences, particularly in context of problem focused policy research.

Nevertheless, many of the critiques provided by post-positivists serve to reveal the potential for 'bias', the ignorance of the role of language in the construction of social meaning, and the potential for the oversimplification of the social world in positivist theory (Fierke 2001, 116–118). Such critiques have been taken on board within my own research design and I have chosen to utilise a multi-focus analysis which helps to prevent over-simplification and the inaccurate interpretation of the meaning and consequences of social phenomena. The work is multi-focus in the sense that it deals with micro-political accounts of the dual-use issue within various political forums. In this context, careful processes allow me to cross-reference and

30 This point is made here to distinguish the Author's epistemological commitments, rather than arguing that methodological post-structuralists should or do engage in securitization research. Indeed, while Weaver, the architect of securitization theory, rather infamously describes himself as a 'post-structuralist realist', he himself has not embraced a post-structuralist epistemology on this issue – see Floyd (2010, 23–28).

31 The term here is used to refer to the type of pragmatism outlined by Katzenstein and Sil (2008, 124), who describe pragmatism as sitting in the middle ground between analytically rigid positivism and relativist subjectivism, involving the application of coherent philosophical principles in the generation of policy relevant forms of knowledge. In particular, the concept is understood to refer to research which aims to '*reorganize, define, connect and solve substantive problems'*.

validate observations made in relation to multiple sources of evidence in the process of developing qualified generalizable rules.

Such epistemological discussion aside, the remainder of this section is dedicated to addressing the question of how this thesis can contribute to securitization theory development; this is despite the charge that more intellectually pragmatic approaches do not contribute to the development of existing theory (Katzenstein and Sil 2008, 124). This involves the development of analytical concepts through the 'pragmatic fusion'(Katzenstein and Sil 2008, 124) of analytical concepts developed within securitization theory, as well as concepts drawn from outside of the field, including concepts from risk governance theory as outlined in chapter two.

### Securitization Studies and Theory Development

Several scholars have investigated the philosophical underpinnings of securitization theory, which has involved identifying political, linguistic, sociological and post-structuralist theories as being important to the study of securitization processes (Floyd 2010, chap. 1; Hansen 2011, 358). Discussion of political theory has included the ideas of Schmitt (1996), who focuses on the distinction between 'normal' low political processes and the 'high drama' of security related political processes – an idea prevalent in the works of Wæver (Buzan, Wæver, and Wilde 1998, 24–26; Williams 2003; Rita Floyd 2010, 17–19). Increasingly, however, there has been focus on the collective nature of decision and policy making in security politics (Wæver 2011, 467). This has emphasised the idea that security policy making necessarily involves more than one actor; therefore, even securitized politics does not normally involve the dominance of a single actor or discourse. Others scholars have identified the importance of linguistic philosophy, specifically 'speech-act' theories, in understanding the process of securitization. Speech-act theory has also been employed as a

theoretical framework for discussions about balancing the role of securitizing actors and audiences in the legitimization of activities which utilise the rhetoric of security, as well as how to adequately incorporate 'facilitating conditions' into the study of securitization processes (Stritzel 2007; Balzacq 2005; Huysmans 2011). Sociological theories have also been employed, and advocated (Balzacq 2010a, 37), in the examination of contextual factors relating to securitization processes. This has included the use of Goffman's (1974) dramaturgical analysis (a type of sociological 'frame analysis') of securitization events, which focuses on how the identities of securitizing actors and their audiences interact in institutional contexts (Salter 2008). Discussions of post-structuralist theory have focused on the discursive construction of security threats, with particular emphasis on the concepts of discursive formation and governmentality. These scholars have tended to focus on the discursive process by which issues are constructed as governable security problems (Stritzel 2007; Rita Floyd 2010, chap. 1; Hansen 2011).

Investigations into the philosophical heritages of securitization theory have demonstrated that it has been successfully applied by a wide range of scholars with a diverse range of epistemic and ontological commitments. This suggests that attempts to develop an underlying, philosophically-grounded theory of securitization perhaps risk creating the misleading perception that there is theoretical unity in the field. Such an endeavour also risks squeezing the field into a Procrustean bed of sociological, linguistic or post-structuralist paradigms, which could unnecessarily limit analytical and methodological scope.

There is now consensus within the field that the existence of such variance must not stunt the ability of scholars to produce new theory that may contribute to the field. This is reflected in the way that early critics of the antecedent Copenhagen approach, as well as members of the Copenhagen school, note the importance of ensuring meta-theoretical means for collaboration

between these between linguistic and sociological approaches to securitization theory (Balzacq 2010b, 26; Balzacq 2010a, 36–37). This is to ensure that securitization theory does not become several relatively discreet sub-fields which can no longer benefit from each other. In pursuit of this goal, two approaches have been advocated.

Balzacq (2010) suggests that both linguistic and more sociological securitization research can be considered to contribute to the study of a broader conception of securitization grounded in social theory. Within this conception, the work of the Copenhagen School occurs mainly at one level of a three level conception of securitization study. At this level, securitization is understood to include acts (including, but not limited to speech-acts), agents (actors' identities and socially constructed objects) and context (agents' interaction with their surroundings). Balzacq's model is useful insofar as identifying the analytical strengths and limitations of various theoretical conceptualisations of the securitization process; it also provides a broadened range of research methodologies (consisting of theoretical frameworks and research methods) that scholars may choose from. However, Balzacq's work is less useful in providing guidance to scholars about how to conceptualise the theoretical contribution of their work to the overall development of securitization theory. This is because Balzacq's approach is heavily informed by sociological thinking and this does not necessarily speak to approaches which are informed by political or linguistic theory.

Wæver offers an alternative approach to understanding the collective project of securitization studies, arguing that securitization is an 'idea theory', meaning a theory with one simple core idea that is used by analysts (Wæver 2011). He argues that researchers should distinguish between the core concepts of securitization and cumulated knowledge from the diverse range of empirical studies in the field. Within this conception, the central concepts of securitization theory (i.e. actors, audiences and securitization moves) are freestanding from changing

practices of security and without underlying philosophical or methodological groundings. This understanding of securitization theory emphasises the importance of developing a set of conceptual tools which can be used by the various categories of scholars identified, as well as in the context of more interdisciplinary analysis. It is this latter approach which allows the appropriate level of flexibility and structure for scholars to contribute to theory development. In the following section I take up the task laid out by Wæver and characterise some useful analytical concepts, which will then be embedded into my own analytical framework.

### 3.4 Securitization and the Potential Utility of Policy Process Models

The previous section highlighted the need for new conceptual tools which can be employed by the wide range of scholars operating within the field, as well as within interdisciplinary case-study analysis. The following section demonstrates how policy process models can be useful in achieving these objectives.

First, they can provide focus, structure and limits within analysis, which are of central importance in interdisciplinary studies, as well as in multi-level approaches, such as that identified by Balzacq (2010a, 36–37). This can help the analyst to identify which factors are and are not relevant with regard to policy outcomes. Second, such tools can be utilised by linguistic focused scholars to overcome a commonly identified analytical weakness of this type of research. This is the issue of adequately incorporating histo-political and contextual factors into the study of 'speech act' events and the production and reproduction of 'security discourses'. Policy models can provide a straightforward institutionally, historically and politically situated 'environment' for discourses and 'speech-acts' to occupy within an overall process of securitization. Finally, policy models also help to make the assumed relationships between central concepts within analytical frameworks more explicit, for example, the relationship between actors and audiences or individual securitization moves

and overall policy outcomes with relation to a given issue. For example, high level 'securitizing' communications to the public are often identified as important within studies of securitization processes; however, there tends to be little investigation into what these acts are actually designed to achieve or explanation of how these activities relate to governance outcomes. The absence of explanation within existing research is based on implicit understandings of the relationship between policy makers and the public. The adoption of a clearly defined policy process model would provide a means for scholars to make their understandings of such relationships more explicit.

Despite the utility of these models to the various approaches to the study of securitization, the discussion of policy process models has been conspicuously absent from the work of Critical Security School scholars, who have published largely in the *Security Dialogue Journal*. It is early-career scholars who have taken up the challenge of investigating the utility of policy process models. This dynamic has favoured tentative explorations, as well as demonstrations of the value of well-known and conceptually parsimonious policy models, specifically multiple streams and linear models. However, it may also be the case that securitization scholars have had sound theoretical reasons for avoiding more complex theories of the policy process. With this latter point in mind, the following section reflects on the range of policy theories available and the suitability of these for use in securitization research.

### 3.5 The Selection of Policy Process Models in Securitization Case Study Research

The primary purpose of policy analysis frameworks has been to help analysts to conceptualise complex political processes which involve a wide range of actors, institutions and discourses (Sabatier 2007, 4). Sabatier has identified several categories of policy models for used in the US and Europe; these are:

**The policy stages heuristic:** Policy is studied as a series of identifiable stages in the overall process of policy development.

**Institutional Rational Choice:** This approach focuses on how the rules of institutions affect the behaviour of rational self-motivated individuals.

**Multiple stream models**: Within this approach policy process is studied as several largely (ideationally and institutionally) discreet streams of activity. The approach is used primarily to help explain why policy initiatives emerge when they do.

**Punctuated- Equilibrium framework:** This approach focuses on the causation and consequences of periodic shifts from instrumentalist forms of policy making to periods of major policy change.

**The advocacy collation framework:** This approach focuses on the development of collectives who share policy beliefs within policy making communities – in essence, this approach focuses on the condition that lead to policy-learning across groups of policy makers.

**Policy diffusion framework:** This approach examines how 'policy innovations' spread between political systems.

**Large N- models:** These approaches focus on macro-variance with states, and the effect on policy (i.e. budgetary expenditures, public opinion) (Sabatier 2007, 8–10).

Sabatier (2007, 3–4) has argued that many of the policy model frameworks can also be used in complimentary ways in applied research. Such a perspective makes sense in more inductive approaches to theory, as each of the policy models have analytical advantages as well as shortcomings, such as blind-spots and analytical bias. It is therefore tempting to utilise a combination of the wide range of models to study securitization processes. This suggests that there is potentially a wide range of ways to conceptualise the policy process within this research, and in securitizing research more generally. However, before selecting a

policy theory model to use, it is worth making explicit the requirements for use within this thesis.

The first set of criteria for the selection of a policy process model are that it needs to be suitable for a comparative small-n research design, which makes up the bulk of securitization research. The comparative nature of the research design does not exclude any of the dominant theoretical frameworks, as many of these have emerged from comparative studies and since been widely utilised as a means to structure comparisons. The requirement for an approach suitable for small-n models leads to the exclusion of several predominant frameworks designed for large N-studies, which can be dismissed due to the well-known differences in the analytical focus of small-n and large-n research designs. In addition, there are in practical terms simply not enough cases, or at least cases for which there is adequate information, to make such comparisons in relation to dual-use governance at national or sub-national level.

The second set of criteria relate to the suitability of the theory for use within inter-disciplinary analysis, as well as for the wide range of academics that employ securitization theory. First, it is required to be suitable for identifying facilitating conditions (historical, discursive, and institutional) and actors, and helping to place their activities in an institutional context. There is no reason why any policy models should be rejected due to this criteria, as policy process models, according to Sabatier (2007, 3–4), all models represent an attempt to take these factors into account, although with varying levels of success.

The second requirement is that the policy model should be simple to apply within analysis; this stems from the low level of explicit use of policy models within existing securitization literature, as well as the need for the policy heuristic to be transposable enough for use in the wide range of approaches to the study of securitization identified above. While traditionally theoretical ‘parsimony’ is seen as anti-ethical to more detailed and rich small-n analysis

(George and Bennett 2005, 31), it is worth reiterating the point that the policy process model described here is understood to be one transposable piece of conceptual apparatus that can embedded in broader theoretical frameworks used in the context of other applied research. In the following section, the two models which have already been advocated within the literature are evaluated according to these criteria. This then informs the development of a synthesised model.

### 3.5.1 Linear Model of Policy Development

The linear model of policy development is best thought of as a heuristic for breaking down complex policy processes into more manageable set of stages (Sabatier 2007, 6). The stages most commonly identified within policy studies textbooks are: 1) issue identification and recognition; 2) appearance on agendas; 3) policy formulation; 4) policy adoption; 5) policy implementation and 6) policy evaluation. Sabatier has also highlighted that many authors of the policy process literature have utilised this heuristic to provide a boundary for the focus of their research, which has led to stage-specific bodies of literature (Sabatier 2007, 6). This model was widely employed in the early stages of the development of the field of policy studies; however, the approach is now understood to be inadequate in the formulation of causal explanation across stages. The approach also risks conceiving the policy process as a single linear process. Despite these limitations, this heuristic provides a straightforward means to group and describe governance activities. Recently Bright (2010) has utilised a simple linear policy model in a single case study. Within this work he also went some way to theorising the ways in which securitization processes may manifest at various stages of the policy process, which were intuitively developed from the ‘special’ type of politics usually associated with securitization. This included:

- Agenda setting – the rhetorical reference to security at the agenda setting stage was understood as a means to raise the issue on agendas.
- The possibility that existing governance structures may be ignored or compromised at the policy formation stage.
- The 'legitimation' of the deployment of significant resources at the implementation stage.
- The use of the grammar of security in the evaluative stage.

This compartmentalisation of the securitization process certainly appears a straightforward way to conceptually untangle complex securitization processes. However, as previously outlined with regard to a general critique of linear policy, this approach risks neglecting cross-stage factors. For example, to what extent can actions at the various stages be considered part of a collective project, and who, if anyone, could be understood to be the driving force behind policy emergence? Another implicit issue with such a framework is that there is still a requirement to conceptualise more explicitly the role of historic, ideational and institutional practices within the policy making process, and this framework alone provides little guidance on how to incorporate these factors. Léonard and Kaunert (2010) have already advocated Kingdon's (1984; Kingdon and Thurber 2010) three streams model as a means to better address some of these issues in the study of securitization. In the following section, the utility of this model to this thesis is examined in detail.

### 3.5.2 Kingdon's Three Streams Model of Policy Change

Kingdon's dissatisfaction with the linear and rational nature of some approaches to the study of the policy process motivated the development of his three streams model. He framed his thesis with the question 'How does an idea's time come?', and sought to develop a theoretical framework which focuses on the role of identities and institutional norms in the agenda setting process. Within Kingdon's model, policy change is conceptualised as consisting of three essentially independent streams (problem stream, policy steam and the politics stream),

which converge at key moments called policy windows. These policy windows can be understood to represent the alignment of political conditions, which allow a policy to make it through the selection process. These policies are usually advocated by identifiable 'policy entrepreneurs' who utilise various types of political resources available to them to get specific policies on agendas. Each of these streams is now outlined.

The *problem stream* involves the identification of a pressing problem that requires attention. In this stream, policy makers begin the process of framing an issue as a solvable political problem. Actors' identification and framing of an issue depends on a wide range of histo-political factors, including actors' identities and events. Actors also utilize a series of rhetorical approaches to convince others to address a given issue. This includes references to causality, severity, recent examples, novelty, as well as attempting to assign the responsibility of dealing with the issue to a target institution (Rochefort and Cobb 1994). Kingdon suggests several routes by which issues may gain attention as a problem: the routine monitoring activities of institutions, dramatic events or studies by government agencies, governmental researchers or academics. It is also worth highlighting that just as problems can emerge within this stream, they can also fade away. There are a number of reasons for this; policy makers may feel that the problem has been adequately addressed (by themselves or others) or actually 'solved', there may be a perception that the problem has somehow ceased to be, or fatigue may set in amongst advocates when it becomes clear that actors of strategic importance will not address the issue.[32]

[32] Based on Kingdon (1984, 2nd:103–104). However, I am careful here in distinguishing between the idea of the problem 'actually' disappearing, and the idea that there is a perception among key actors that the problem has disappeared. This is especially important in more systemic and complex issues, as compared to say 'brute' problems with directly observable causation and effects, such as the 'millennium bug' problem which almost instantaneously disappeared on the 2nd of January 2000, or the complete eradication of a specific disease such as the agricultural Rinderpest virus. See also Floyd (2010, 32–33) on this issue, who distinguishes between the idea of 'brute' threats and constructed threats.

Kingdon pinpoints ‘policy communities’ to be of central importance to understanding the policy stream. Policy communities are usually well-networked and operate according to values and norms that may be quite distinct from other policy communities as well as from other stakeholders. Within this thesis, the term ‘policy domain’ has been used in order to capture the dominant discourses, institutional settings, practices and favoured governance tools utilised within a given policy making environment that have impacted upon dual-use governance (NEST, anti-terrorism, public health, biosafety). Within each of these domains, decision makers identify potential solutions and select ‘appropriate’ policies based on criteria such as technical feasibility, value and the extent to which they can be sold to strategic audiences such as politicians and other policy communities (Kingdon 1984, 2nd:125–143). This can lead to the identification of a single policy or short-list of potential policy options which may vary in nature depending on the level of ‘fragmentation’ in relation to a given issue within a given domain (Kingdon 1984, 2nd:118–121). In cases of more diverse fragmentation, ‘competing’ policy proposals may be developed. It is worth highlighting that institutional path dependency and ideational factors can be understood to have a particular impact upon the decision process at this level, as this is the stream in which the fine details of policy programmes are developed and refined.

The *politics stream* is heavily associated with ideas of legitimacy, power and persuasion. Kingdon identifies several important facets of the political stream, including public mood, pressure group campaigns, election results, ideological distributions in political institutions and changes in administration and powers, and institutional relationships (Kingdon 1984, 2nd:145–165). In essence, these factors impede or facilitate actors in building strategic coalitions of decision makers in pursuit of implementing a particular policy. The *politics stream* can have more of an effect on the policy process in certain situations. Politically

controversial issues which are likely to emerge suddenly and dramatically seem to increase the role of the political stream in the policy process. This impact can be both facilitative (i.e. increased funding) or deleterious (i.e. rejection of long standing policy approaches in favour of something new). In contrast, when issues don't receive public or policy maker attention, and an issue is successfully argued (if it even needs to be) to fall within the remit of an existing governing institution, then the politics stream becomes much less important (unless extra resources are required to deal with a new issue).

The three streams theory provides an explanatory framework for the emergence of a given policy initiative. At certain historic moments, conditions are right for a policy to be developed and implemented. These moments are referred to by Kingdon as 'policy windows'. These selection pressures may be heavily institutionalised, meaning that the approach leads to a relatively deterministic policy process. However, within Kingdon's framework, individual agency is also understood to play a role in the emergence of policy. Policy entrepreneurs, who may work from various positions inside and outside formal politics, are understood to play various roles within the administration literature. These include:

- *Advocating new ideas and developing proposals*: These may initially be free of existing institutionalised governance structures.
- *Defining and reframing problems*: Often with specific actors or domains of government in mind.
- *Specifying policy alternatives*: Particularly in the context of issues seeming to require collaborative governance, where there may be several possible ways for the same issue to be governed.
- *Brokering ideas among the many policy actors:* This is in order to build a coalition of support.
- *Mobilizing public opinion:* This is in order to create the right political environment for a given policy.

- *Setting the decision making agenda*: This involves identifying decisions and agreements that need to be made in the process of developing and implementing policy.

(Roberts and King 1991, 152).

Criticisms of the multiple-stream model

Zahariadis (2007, 80–83) has highlighted the key criticisms laid out against the use of multiple streams framework. The first relevant issue relates to the scope of the framework, particularly in the context of the appreciation of the multiple stages of policy making. This is because the model was initially developed for the study of the agenda-setting state of policy making. Kingdon, as well as several other scholars, has successfully applied the framework to various stages of the process (Zahariadis 2007, 80). Heuristically, there is no reason why the framework can't provide an initial structure to analysts at the various stages of the policy making process. These stages can then be used to structure observation related path dependency, framing effects and institutionalisation. This can be considered a strength rather than a weakness of the approach, as it provides a heuristic to investigate the role of different actors, discourses and institutions at various levels of the securitization process.

A second charge made against the framework is based on the claim that streams are less independent than the heuristic would suggest. This may well be the case; however, careful process tracing and elite interviews can reveal points at which these streams interact. This characteristic may be an advantage in the context of a securitization research, as it is widely agreed that securitization can involve actors breaking the normal rules of politics. For example, securitization may involve developments in the politics stream impacting upon norms or practices within a given policy stream to an unusual extent. An obvious example of this would be the provision of more resources for biodefense based on decisions made in the political stream, which led to more ambitious projects being considered within the policy

stream. Therefore, the points of interaction between streams, for the purposes of this research, can be conceived as an aspect of analysis rather than a limitation if it is adequately acknowledged.

A hybrid of the three streams and linear models: Incorporating agency ideas and institutions into the securitization process.

Leonard and Kaunert (2010) have already argued that policy process models, such as the three streams model, can provide a clear conceptualisation of securitizing actors and audiences, including the relationships between the actors and the overall policy making process. Likewise, Bright (2010) has argued that securitization theory can provide expectations of how the rhetorical deployment of security will affect specific policy processes. I have also demonstrated that policy models can be developed and utilised in a way that draws attention to structuring factors (such as identity, discourses institutions) at various stages of the policy processes. Specifically, I have outlined how linear and the multiple streams model can be utilised in a complimentary way within empirical research.

To sum up, this model provides a straightforward heuristic, designed with the requirements of securitization scholars in mind, with sufficient structure to help analysts identify important agency intervention points as well as the role of key histo-political factors in the emergence of policy. This is achieved without unnecessarily constraining the scope of analysis, a charge which has been made against discipline-specific attempts to contribute to the development of the field. In the following section I utilise this model for the development of my own analytical framework.

### 3.6 Analytical Framework for the Study of the Securitization of Dual-Use Issues

In this research, the aim is to make claims about the role of security politics (understood to refer to actors, discourses and institutions) in the emergence of the distinct dual-use governance assessment regimes that have emerged within the UK and the US. Other research into securitization processes has not always made the governance of a specific issue the focal point of research. The original analytical framework of Wæver in *Security: A new framework for analysis*, for example, focuses on 'sectors' (military security, environmental security, economic security, societal security, and political security), which were utilized to distinguish the 'rules' of securitization in relation to a broad range of issues which had emerged on the security studies agenda in broader policy domains (Buzan, Wæver, and Wilde 1998, chap. 1). Within my own work, however, the focus is on a much narrower set of institutions and discourses. This means that I am examining the process and consequences of securitization with the aim of discerning some 'rules' of security politics (i.e. who securitizes, what do they securitize, under what conditions and with what effects) in relation to the dual-use issue. In this respect, my preoccupations align more closely with those scholars who have utilised securitization theory to examine how 'logics of security' (i.e. discourses associated with the national security domain) , 'security practices' (i.e. policies of control usually developed and prevalent the national security domain) and the 'politics of security' (i.e. the 'emergency' political processes associated with securitization) have impacted upon the emergence of specific policies directed at a given issue (Hansen 2011; Rita Floyd 2010; Cook 2010; Emmers 2009; Hameiri and Jones 2013).

Securitization and the subject of governance

All manner of issues can be constructed as security threats; however, within case studies it usually appears that some rather specific (even archaic) aspects of a much broader field are identified to be of dual-use concern. This then leads to questions about the political and

discursive process through which the scope of such concerns have become set, or at least dominant, within the discourse. As has already become clear, claims about the scope of problems and the nature of responses are likely to be heavily influenced by pre-existing governance domains. However, emergent issues can also be understood to challenge existing predominant practices and styles of reasoning. Simply put, one approach to thinking about dual-use issues is to prioritise pre-existing governance frameworks when thinking about the scope of dual-use problems. A second is to emphasise imagining new scenarios of misuse which can't be addressed by existing frameworks. The latter approach tends to generate concerns which cannot be addressed purely through incremental improvements to existing governance systems. A key question in the context of this thesis is the significance of these approaches in the emergence of dual-use policy and national styles of dual-use governance. With this in mind, it makes sense to briefly characterise these two types of logic:

> *Scenario heuristics* involve interrelated (and often implicit) assumptions about the intentions and capabilities of misusers, as well as the misuse potential of science and technology. Such heuristics may also emphasise 'possibility' rather than 'probability' (Vogel 2006). As these scenarios are generated outside existing regulatory frameworks, there is likely to be an absence of conventions to quantify such issues as risks. This means that such scenarios are often associated with 'precautionary' styles of reasoning and may be articulated as part of a call for anticipatory responses in the absence of scientific evidence.
>
> *Pre-existing governance rationalities* set the scope for dual-use problems with reference to foreseeable coverage given by existing or emerging systems of oversight. These framings place greater emphasis on the resilience or adaptability of existing or proposed systems in addressing the dual-use issue. Such approaches also tend to

discount misuse scenarios which cannot be addressed through modest adaptions of existing governance systems.

The identification of these styles of reasoning and argumentation within the discourse can provide only a partial understanding of the political processes which underpin the emergence of dual-use governance. In the following section, the analytical framework utilised to address this question is outlined.

Securitization and the question of how and why issues become subject to governance

In this thesis, the question of 'how' an issue becomes subject to governance is understood to relate to the mutually constitutive ideas of agency and structure. This question comprises of a series of interrelated sub-questions related to the means by which human agency impacts on the emergence of dual-use governance, as well as the enabling, structuring and constraining histo-political and ideational factors which give impetus, meaning and limit to the scope of this agency. This understanding is in keeping with a more 'mainstream' or 'consistent constructivist' approach[33] to the study of security. It can be usefully contrasted to more language focused approaches which concentrate on linguistic features of securitization 'events',[34] or on the linguistic processes through which actors construct security threats. It is also in contrast to more micro-sociological explanations which focus exclusively on the way in which security and securitizing practices are reproduced by actors in a given context. In this respect, I follow the approach of those scholars who have emphasised that the study of 'emergency policy' should not be restricted to a focus on an enabling step which justifies 'dramatic emergency measures', or acts purely as a system for maintaining a state of

[33] For more on the idea of consistent, or mainstream constructivism in securitization theory see: McDonald 2008; Thierry Balzacq 2009. For more on constructivism more generally see Fierke and Jørgensen 2001. This issue is also discussed in Fierke 2007, 181–182.

[34] The term 'securitization events' is sometimes used with a negative connotations by constructivist scholars, such as McDonald (2008, 576), who associate this with the analytical narrowness of studying rhetorical acts of securitization.

emergency politics. These scholars argue that security politics should not simply be studied as a symbolic watershed moments, involving a distinction between 'normal' and 'emergency' politics. This is because such an approach creates an artificial and analytically unhelpful dichotomy between security and normal politics (Fierke 2007, 187–190). Instead, security politics can be studied with much greater reference to the institutional/governance context in which all policy is generated, including situations where policy appears draconian or unprecedented.

As has already been outlined, securitization scholars have so far tended to study either the emergence of specific security policies or the impact of 'emergency' politics in relation to a given issue area. However, both of these types of securitization may be studied as part of a single case-study. Below, distinctions are made between 'primary politics' and 'secondary politics' in securitization processes, both of which are subject to study within this thesis.

> **Primary politics**: Securitization is sometimes thought of as a form of political crisis in which institutionalized elites mobilize in response to the issue. Vuori (2008, 72) explains that, in times of crisis '*securitization processes may be restricted to inner elite audiences and struggles.'* Thus, policy *windows* open for would-be *policy entrepreneurs* who are in the right place at the right time, and who may attempt to develop policy responses within this closed environment.[35] While there may eventually be pressure on parties from various stakeholders to 'open up' policy development in western democratic countries, early responses to crises, especially in relation to the threat of terrorism, are almost always dependent on the decisions and resources of the state. These situations prioritise the role of political elites early on in

[35] Leonard and Kaunert (2010, 68) have suggested that policy entrepreneurs are closely related to the concept of securitizing actors. I agree, although as has already been argued within this work, this is not to suggest that identifying an 'entrepreneur' means that the 'cause' of securitization has been fully explained. Such explanation would require reference to broader political conditions.

the shaping of the process through framing and path dependency effects.

It is worth highlighting at this point that, while retrospectively many primary securitization moves appear urgent, drastic, and even draconian in nature, these policies were not necessarily advocated for 'irrational' reasons by the actors. This appears to be a tendency in the thinking of some scholars who have applied securitization theory. This distinction also makes the question of '*why*' actors engage in primary securitization more meaningful.

A more useful approach to thinking about primary security politics is to frame it as a political process which shapes the rules, defining which future decisions are made in relation to a given topic. This may involve, for example, the establishment of a legal framework which gives power to an institution to make a decision, or implement policy on a given issue. It might also involve the establishment of broader political process designed to generate policy on an issue in the future. Primary securitization, then, essentially involves the formation of agreements, though consensus or coercion, over the rules by which policies are made in the future, including the rules about who participates in the process and how.

**Secondary politics:** This involves the process through which policy options are developed, articulated and implemented in the context of agreements about the overall process of policy development. It will usually involve the application of existing governance frameworks to a given issue by an established regulatory body. However, this may also involve sui generis governance activities when a new channel of policy development has been opened up (perhaps through a primary securitization process).

The study of secondary politics involves analysis of the historical and political factors

have impacted on specific policies throughout their life cycles. This includes, for example, how actors have strategically engaged with policy development and implementation processes, as well as the identification rationales which have been utilized to inform and challenge policy initiatives. In also includes reference to the role of the broader political environment in supporting or hindering specific policy initiatives.

Another key question within securitization literature is how analysts can make defensible claims about the motivations of actors who engage with security politics. For clarity of explanation, and in-keeping with the trend within the field, I approach this issue with a focus on the securitizing actor. However, answering this question is ultimately understood to relate to the agency of all actors involved in security politics, including those who resist securitization. The question of 'why' actors securitize has been approached in various ways by scholars of securitization, who differ on ontological and epistemological grounds. Gad and Peterson(2011) have argued that over the previous decade, the issue of 'intentionality' has been understood by securitization scholars in three ways. Their way of grouping securitization research is utilised below to explain how the issue of intentionality is understood within the thesis.

The first understanding is that securitization involves actors in a position of power making a decision to secure a referent object through a securitization move. Within this understanding, securitizing actors wilfully decide to construct an issue as a security threat and communicate this decision to audiences, who either refute or accept this claim (Pram Gad and Lund Petersen 2011, 318). This approach to understanding the securitizing move emphasises the 'top-down' or 'imposed' nature of successful securitization, as it does not account for the role of audiences in the production of the security threat. Within this understanding, the agency of

audiences is reduced (they can only receive the communication and make a decision to accept or refute it), and the agency of the securitizing actor in emphasised. Securitizing actors 'design' a securitization move based purely on their own purposes, but tend to frame their communication in a way that ensures support. This understanding has led to more critical scholars, such as Floyd, to seek ways to normatively evaluate securitization moves based on the distinction between what actors claim to be doing when they securitize, and what they actually do (Rita Floyd 2010, 1–2).

This approach neglects the idea that, in the process of policy development, actors (including audiences and facilitating actors) may continue to exert their agency following a securitization move. To claim that successful securitization always involves command and control type policy implementation, orchestrated entirely by the unchangeable will of a single securitizing actor, seems to set the bar for 'successful securitization' impossibly high in the context of modern democracies, where securitization policy necessarily involves a wide range of actors and institutions in the overall policy process. To give an example, a securitizing actor may initially choose to implement a certain policy, and all relevant audiences may agree, but during the process of policy implementation, actors involved in the process may convince the securitizing actor that the implementation of this policy must be modified in some respects to be feasible.[36] This suggests that while securitization moves may involve the dominance of actors and discourses, the outcome of securitization should still be studied as the result of collective action, rather than as a process by which issues are lifted above the political in the context of modern democratic states.

[36] This approach also (perhaps unfortunately) raises questions about the critical approach of Floyd referred to the in the previous paragraph, as from a more cynical perspective it provides a rich seam of potential excuses for why securitizing actors don't always act as they say they will.

The second approach is closely linked with Ole Wæver, the founder of the CS school, who has remained influential in debates within the field. According to this way of thinking, securitizing actors and audiences in effect agree on rules about the future discussion of a given threat. The way in which agreements between the securitizer and audiences are reached is through a linguistic process, or 'event', which results in an acceptance of a shared discourse of securitization. Within this conception, there is no scope for assessing reasons that actors securitize aside from the communications between these actors. This understanding is very much restricted to the study of the intentions of actors in securitization processes and confines the study of securitization processes to discourse analysis, usually of public texts.

Wæver's decision not to address actor intentionality in relation to the securitization processes is based on post-structuralist leanings within his thinking (Floyd 2010, 10–32), rather than been an essential aspect of the securitization 'idea theory'. To explain this point further, Wæver chooses to follow a more Derridian post-structuralist conception of what should be the appropriate focus for analysis in the study of securitization processes (i.e. 'texts'). This is in contrast to the approach of IR scholars, such as Adler, who focus on the individual motives and interests of actors.[37] Wæver's decision, then, reflects his own underlying philosophy, rather than a definitive aspect of the 'idea theory' of securitization. This means that the founding figure's analytical framework cannot be understood as the 'only' way to understand the phenomenon of securitization. Indeed, there has been sustained criticism of the inadequacy of Wævers particular framework, especially from sociologists and constructivists (Williams 2003; Balzacq 2005). Rather than rehearsing these criticisms once again here, it is worth concluding with the point that the Wæver's approach does not attempt to, and without

[37] For more on this issue in relation to constructivism more generally see Fierke (2001).

serious reformation,[38] is unable to address questions of agency, which damages the approach irreparably with regard to addressing questions about histo-political context. Despite these shortcomings however, Wæver's position on this issue continues to be an important reference point when securitization scholars address the question of why actors securitize in contemporary work.

The final approach, typified by Balzacq (2005), emphasises micro-sociological accounts of how actors continually reproduce structures in the processes of securitization.[39] The approach also emphasises the importance of studying agency and structure as mutually constitutive contexts. However, the issue of why actors securitize is not directly addressed by this framework. In this respect Balzacq exhibits a similar disposition Wæver, in that the motivations and intentions of actors are largely ignored.

With the above discussion in mind, I now develop my own approach to addressing the question of why actors securitize. In the context of this research, I understand the question of 'why actors securitize' to involve analysing the behaviours of actors in relation to the goal of developing policy, which usually involves the application or extension of existing policy practices. This could be understood to create an incremental/institutionalist bias within the analysis, as securitization moves are always understood in relation to the governance structures that they alter, rather than the unspoken intentions of the actor. However, the ultimate goal of most securitization is usually a sort of institutionalisation; therefore, it makes sense to focus on the relationship between securitization moves and existing institutionalised norms, values and practices in defining the political purposes of securitization. The focus of

[38] An attempt from a sociological perspective to reform the nature of the speech-act is made by Balzacq (2010a), for example, although the purpose of this, as alluded to in earlier in the thesis, was to develop a more sociological account of securitization.

[39] An example is Salter, Mark B. 2008 'Securitization and Desecuritization: a Dramaturgical Analysis of the Canadian Air Transport Security Authority' Journal of International Relations and Development 11 (4) (December): 321–349. doi:10.1057/jird.2008.20.

analysis is the identification of which pre-existing policy objectives are embodied in actors' engagements with the process of securitization. Below I identify two central focal points in the analysis of why actors engage in securitization processes.

- **Pragmatic actions and interests**: This relates to the short-term goals and actual practices of individuals who are involved in the emergence of securitized policy. This is most obviously epitomised in the case of the '*policy entrepreneur'*, who *may* seek to get an issue on an institutional agenda or secure institutional support, for example, but it also relates to those actors who are central to the implementation of policy at later stages of its emergence. These actors may utilise security rhetoric in various ways in pursuit of pragmatic goals (i.e. convincing others to act, portraying favoured policies in a favourable light to others to favour the adoption of these policies, closing down debates and legitimating existing practices). The pursuit of pragmatic interest in relation to securitization processes can be understood in the context of the overall policy model. Pragmatic acts of securitization can occur at various levels of the policy making process, and within different streams. The question of how these actors go about achieving these goals (i.e. coercion and argument) can also be addressed at this stage.

- **Institutionalised practices, interests, values and favoured policy responses:** These activities depend largely on the values of '*epistemic communities'* of policy makers in the identified domains, to include institutionalised norms of engagement within the securitization process. In essence, this reflects many of the 'default' basic positions relating to a given issue area, such as being 'pro-regulation' or 'anti-regulation'.

Under what facilitating/structuring conditions are dual-use issues securitized?

In this work, the study of security politics primarily centres on the study of the political processes which led to the emergence of policy in relation to the dual-use issue. This has considerable impact on how the concept of 'facilitating conditions' are understood here, to the extent that the term 'structuring conditions' is utilised in place of Wæver's term. In the following section I introduce how this analytical concept is defined within this thesis.

There are essentially two key ways of understanding the impact of structuring conditions within the securitization literature. The first understanding is typified by the work of Wæver and Buzan in *Security: A new framework for analysis.* According to understanding, structuring conditions are crucial to the success or failure of a securitizing 'speech-act'. The speech act consists of a rhetorical act in which something is agreed and achieved using words by an actor, for example, in the naming of a ship. For these scholars, the success of a speech-act represents a watershed moment, the point at which an issue is lifted above the realm of 'normal politics' and into the realm of 'emergency security politics'. Within this conceptualisation, facilitating conditions are understood to be influential at the moment of a securitization 'event, for example, at the point at which a state-department convinces the cabinet that an issue presents a threat in an official communication. A key issue with this approach is that it narrows the focus of analysis to the study of a series of symbolic watershed moments within broader the political process.

The second approach to the study of security politics is to conceive it as a broader political process, embedded in the wider political context (McDonald 2008). This widens the attention of analysis beyond texts, accounting for the institutional and political processes through which texts are generated, as well as for other political activities which are not necessarily embodied in texts. It is this latter approach that is adopted within this work. A typology of structuring conditions identified within this research is laid out below; these structuring

conditions can each impact across the various stages of the policy making process, and within various streams of policy making.

a) Institutional path dependencies: These include historical explanations and possible policy implications of the existence or absence of the capacity to identify or respond to a given issue, or the prevalence of particular ideational values within an institution. An example would be the reasons for the prevalence of nuclear physicists in decision related to the misuse of biological research and technology making in the US immediately following the terrorist attacks of 2001. Another example would be the reasons for and extent to which there were pre-existing institutional relationships to build upon in the development of dual-use policy.

b) Political fragmentation and polarisation in relation to an issue: This relates to the extent to which there is disjointedness within and amongst policy making communities which tend to be in agreement about the ends of policy, even if not the means. This disjointedness may be understood to manifest along ideational or institutional divides. Political fragmentation can lead to uncoordinated and seemingly paradoxical policy/decision making; that is to say, there may be a situation where the right hand does not know what the left hand is doing, or where there is open conflict over preferred approaches (Roberts and King 1991, 119). An example of this would be disagreements within the public health community about either engaging in threat analysis research or limiting the biodefense imperative in the US. Political fragmentation may also in itself be a motivation for securitization moves at various levels – it can act as a means to discredit opposition or rally support, particularly in the absence of agreed criteria to quantify the immediate threat. Within this work, political fragmentation is studied within domains well as well as with in processes of policy emergence.

c) Ideational and discursive factors: The final factor relates to the discourses that structure the deliberative process of governance in each of the cases. This is not only in regard to the central assumptions in the construction of dual-use issues, but also the way in which debates about dual-use issues are structured (i.e. as a dilemma, as a risk as a threat, etc.). In examining this aspect, it is useful to draw upon Hansen who suggests three concepts of value to the study securitization processes (Hansen 2011, 359):

> *Structural incorporation*: This refers to the use of signs (such as things that are generally held to be threatening) in the construction of problems. For example, the dual-use issue has been governed as the novel manifestation of an existing category of problem within the governance domains identified (i.e. terrorism, safety, societal backlash against science, infectious disease).
>
> *Epistemic terrain:* This refers to claims based on assertions or assumptions. That is to say, for example, what is 'known' about the dual-use issue, as well as what is 'known' about the field of synthetic biology, and how this knowledge is synthesised in the generation of dual-use problems.
>
> *Substational modality*: This refers to claims about the set of norms, rules and values which should be used to evaluate and govern the threat. Within all domains of dual-use governance, it is either implicitly or explicitly asserted that the issue requires some sort of response which is in keeping with or an extension of the existing governance discourses within the domains identified. There are, however, perhaps disagreements about how the dual-use issue should be conceptualised, which may have served to frame debates in national contexts (i.e. whether the issue is a risk, an ethical dilemma or a threat). For example, claims about the ability to make scientifically sound risk/threat assessments may be central to the

deliberative process (Villumsen 2011; Van Munster 2005; Aradau and Van Munster 2007).

In securitization processes, it is likely that there are many central assumptions shared amongst the various stakeholders who chose to engage with the dual-use issue. In understanding the structuring conditions of the securitization of dual-use governance, it is essential to map and characterise the nature of these agreements. Having addressed these analytical issues, the remainder of this chapter is dedicated to outlining the methodology for this study.

### 3.7 Methodologies and Study Design

The scholars who have dedicated their studies to the dual-use issue represent a broad and quite transient church, which has included the fields of applied ethics, arms control, political science, sociology, anthropology, science and technology studies, and security and strategy and defence studies. There is now quite a substantial body of literature which directly addresses the concept of dual-use governance; however, there is a clear absence of discussion of socio-political epistemology and ontology within this area. Indeed, the absence of such theoretical considerations made the dual-use issue such an interesting topic for Rappert (2009; 2007), who was one of the first to highlight the constructed nature of the dual-use problem, and articulate the challenges it posed as a subject of research. However, such questions have often been second to more immediate questions facing policy communities and academics about what needed to be done, and how. To this end, much research has focused on the implementation of specific policies (such as education and awareness-raising within the scientific community) or the development shared definitions of the dual-use issue. For example, Miller, Selgelid and van der Bruggen (2011, 8) sought to '*develop an acceptable, adequate and applicable definition of the dual use concept for researchers,*

*universities, companies and policy makers [as]….a clarification of the dual use concept and its scope of application would greatly facilitate the work of policymakers…'*. In addition to this, dual-use issues have increasingly appeared on the fringe of more long-standing academic and institutional agendas, particularly in relation to the BWC regime and increasingly in the context of ELSI agendas. This has resulted in a nebulous body of academic and policy literature addressing the topic area.

It became apparent during the literature review that a thesis provided an appropriate opportunity to develop a more systematic approach to the study of the issue, which could synthesise existing research, together with my own findings, into a more coherent whole. A key part of this process was the development of an analytical framework for the study of the practice and politics dual-use governance, which involved consultation with literature on bio-security politics and practice, as well as more general texts on the study of policy, risk and, in particular, securitization theory. In the approach described below, the methodology through which this framework was operationalized as a research project is outlined.

Within this thesis, a theoretically structured comparative case study approach is adopted; this is well suited to the inductive aims of this research (George and Bennett 2005, 19–21). The cases have been chosen according to the divergent nature of governance processes and outcomes (i.e. policies, governance activities). This is because cases that diverge in relation to a variable of interest are especially likely to reveal important intervening variables (George and Bennett 2005, 21). In this case, the variables of interest are practices, politics and security rhetoric which are understood to be distinct in relation to dual-use issues in the US and the UK. Added to this, the political developments within the US and the UK in relation to synthetic biology are also likely to become archetypal in future debates about the governance of other techno-scientific fields.

Although the small-n case study approach is well suited to this research, it is worth briefly outlining the potential limitations of the methodology, and how these have been addressed in the study design. Selection bias can hinder the ability of a researcher to make generalizable claims about other cases of interest in this type of research. However, this study is the first major investigation into this area and is primarily aimed to be exploratory. The main focus is the identification of important factors within the policy development process in each case, and this may be of use to future researchers who study dual-use governance in relation comparable technologies, time periods or perhaps states. Another claim often made against small-n case studies is the ability of the researcher to assess the impact of the variables identified. While it is important to accept the limitation of findings, a process-tracing element in comparative research can certainly help the researcher to make tentative claims about which variables should be considered important, and those which should be discounted (George and Bennett 2005, 22). Careful process-tracing can also address the concern that the case studies are not independent. This is a concern within this research, as there are many inter-textual links between policy documents in US and the UK. Certain individuals and institutions have also impacted upon both case studies, and within ostensibly discreet political processes. Process-tracing can ensure that such relationships are uncovered and acknowledged within the research. During the literature review for example, it became clear that debates within the UK have been shaped by developments within the US and that it was likely that US experiences had discernible impacts on developments in the UK. Process-tracing was utilized in order to delineate the political significance of these links.

With regard to research methodologies, document analysis and elite interviews are utilised in this study. The approach to document analysis is informed primarily by theoretical and methodological texts within the field of critical discourse analysis (Fairclough 2002; Locke

2004; Wodak and Meyer 2009). This work emphasises the need to examine the context of text production, the purposes these texts are intended to serve, and the significance that becomes attached to such texts during political processes. As has already been outlined within the theoretical chapter, in relation to the study of security, such texts can serve a variety of pragmatic purposes but are at the same time informed and structured be prevailing discourses. In the context of process-tracing, analysis involves making explicit these features of reports and other texts as part of a broader political process as conceived by the analyst.

In addition to document and literature analysis, this research makes use of a series of semi-structured interviews, carried out over the phone as well as in person, at scientific and policy conferences, as well as more informal discussions which took place in meetings and social events associated with these meetings. My experiences of carrying out interviews for this research are discussed below.

Of particular significance within this thesis are the documents which reflect growing political consensus on problem definition and action, and also documents which seek to communicate such consensus to others. Likewise, internal inconsistencies, tensions or 'problem narrowing' within documents can at times also be linked to underlying political disagreements, or to prevailing understandings of the difference between those responses which would be ideal, and those which are understood to be politically feasible.

On top of document analysis I conducted a series of recorded in-depth elite interviews. These elite interviews were also complimented with dozens of informal discussions, and email correspondence, with key individuals. Such informal discussions often occurred on the fringes of international when the opportunity arose. I made a decision early within my project to protect not to identify all my interview subjects. This reflected a desire to ensure that interview subjects could feel confident enough to engage in frank discussions about the

politically charged issue area, without fear of professional repercussions. Within this thesis, such interview subjects are identified in such a way that does not make them immediately identifiable.[40] Elite interviews are understood to complement literature and document reviews in several ways. First, the approach may be used to corroborate what has been established from other sources. Second, elite interviews can help with the reconstruction of key events in political processes. Third, elite interviews can establish or corroborate the underlying interests and/or assumptions of key actors. Finally, elite interviews can yield other sources of data, or provide an assessment of the relevance or impact of documents that have already been identified as important by the analyst and other researchers (Tansey 2007).

Occasionally, potential interviewees flatly refused to be interviewed, did not interview after agreeing to interview, or did not respond to emails after initial face to face contact. In the main, however, both scientists and policy shapers seemed eager to discuss their perspectives and experiences. This was to a great extent facilitated by the use of a semi-structured interview approach, which allowed participants to focus on their own areas of knowledge. The semi-structured interview approach also gave responders the opportunity to query my line of questioning if they thought I was encouraging certain types of answers.

Within the interviews, I ensured that I presented myself as an academic interested in the process of governance, rather than being interested in advocating a specific position, or criticising specific groups or viewpoints. I was particularly eager to do this given the contestation over the role that social scientists were already understood to be playing within the governance process (Calvert and Martin 2009). I was also aware that some interview

[40] Anonymised transcripts of these interviews discussion are available upon request. Such censorship, has placed extra pressure on me to validate claims and perspectives expressed in interviews, or 'off the record' with reference to publicly available evidence. Something which is apparent throughout the analytical chapters.

subjects may have perceived me as having a specific political agenda because of my association with the study of security, and particularly with the politically contested idea of bioterrorism. The main motivation for taking such care was a fear of antagonising interviewees and causing them to 'close-up'; as Rappert (2007) has highlighted, taking only modest positions to encourage conversation is a valuable interviewing technique. Generally speaking, however, most people interviewed were happy to offer a frank description of their own personal experiences and perspectives in relation to the issue.

Interview subjects were identified in several ways. First, it was apparent that it was essential to identify key individuals within UK and US policy processes. This was primarily achieved by contacting authors of key reports, as well as individuals who represented institutions in the wide range of conferences that have addressed dual-use issues. From the outset, it was clear that there were likely to be divergent perspectives amongst policy shapers on these issues, and so the interview set represents contributions from as wide a range of institutions active in the process as possible. Interviews were also conducted after recommendations from other interviewees. The central themes of these interviews were individuals' understandings of what constituted dual-use aspects of synthetic biology, as well as their experiences in relation to the governance of the dual-use issue. On top of interviews, numerous experts were also contacted directly via email in relation to specific questions.

A commonality among the synthetic biologists interviewed was that they all had at least some awareness that there had been public, government and community concern about the dual-use potential of the field of synthetic biology. The term 'dual-use' did not always elicit immediate recollection of the issue among the respondents and other scientists I spoke to. However, the mention of terrorism was usually enough to prompt an opinion on the governance of or likelihood of misuse of aspects of the field. In the interviews and discussion

it also became clear that newcomers to the field were struck by the high levels of biosafety and biosecurity discussions in relation to the field of synthetic biology. Some scientists also raised the prospect of specific applied research based solutions to dual-use and broader biosecurity concerns without prompting.

While many scientists were happy to discuss the dual-use issue, some were less willing to go 'on record' or to discuss the issue in any real depth. Other scientists, while polite, also often seemed indifferent to the issue. One publicly funded scientist who had recently published a collaborative paper on the dual-use issue as part of project funding requirements, also claimed that the dual-use issue had *'all been dealt with'* back in 2006, and then terminated an interview which had initially been agreed to. Another scientist, who is prominent in a private polynucleotide synthesis company, stated that the issue was '*very important'* but was unwilling to be interviewed.

Other interview subjects included: a research scientist who worked for a consultancy firm contracted by the DHS involved in dual-use assessment, two high-level policy shapers from the HHS and the NIH, an early advocate of polynucleotide synthesis biosecurity governance, a technologist who had been engaged with the field of synthetic biology from an early stage, individuals involved in report writing process at institutions such as the Royal Society and Royal Academy of Engineering, as well as individuals involved in international diplomacy related to biological and chemical weapons and public health.

Each of these individuals felt much more confident in discussing the dual-use implications of fields such as synthetic biology than 'scientists'. However, a key theme in responses from those involved with policy was that there were divisions in knowledge, particularly between scientific and security expertise that existed between front-line scientists and policy makers.

These silos also seemed to exist between institutions involved in the policy making process.[41] As a consequence, scientists and policy makers often only felt comfortable discussing or expressing opinions on specific aspects of the broader dual-use issue. This often meant that discussions focused on specific misuse scenarios (usually sub-state rather than state level terrorism) or a specific type of policy (such as education).

Another issue faced during the search for interview subjects was the issue of secrecy. In relation to state secrecy, one leading academic synthetic biologist I interviewed went as far as stating that *'I don't think you will get an idea what's going on…. anything in the US is classified, yeah, and I doubt you'll get any idea at all.'* Such sentiments seem to be something of an exaggeration given the number of public collaborative biosecurity initiatives occurring within the US in particular. Commercial secrecy also occasionally caused problems; on one occasion a non-disclosure agreement was requested in order for me to visit a lab, which created a hindrance to all involved. Added to this, in the private sector, where there are defined channels for public engagement, scientists appeared cautious about discussing policy issues without permission. One prominent scientist associated with the Craig.J. Venter institute, while happy to discuss things 'off the record', was unwilling to be recorded as part of the interview process, stating in response to the request that, '*he liked having his job*!'. Generally speaking however, the process of engaging in interviews and discussions with key experts, emphasised for me the collaborative nature of the relationship between arms control and non-proliferation academics and policy makers in dual-use biosecurity. An idea which is certainly reflected in the number of collaborative projects and publications involving both academics and policy makers. There was also familiarity between scientists and those scholars that study them present within the field of synthetic biology. Such familiarity, was based part on the research occurring both scientists and social

41 This issue was first raised by the ICRC as early as 2004.

scientists within the major synthetic biology research networks and institutions. This familiarity was reflected not only in my interviews and discussions, but also in many of the meetings I attended which included input from scientists as well as social scientists and policy makers.

It is also worth highlighting that many of the scientists I interviewed or had discussions with had often already discussed dual-use issues in the context of academic ELSI initiatives or as part of research conducted by other scholars looking at dual-use issues. This suggests that research in other fields on dual-uses issues, which have not been subject to such media and social scientists attention, may present a more daunting task than synthetic biology for future research on dual-use issues.

### 2.8 Conclusions

Within this chapter an account has been provided of the analytical framework which has been developed to address and refine my research questions. It has been argued that certain aspects of this framework may be of use to other scholars examining security politics, particularity in relation to issues involving complexity, contestation and uncertainly.

Added to this, there was also an account of key challenges faced in identifying, collecting and analysing evidence within case study research in this issue area. These discussions were not designed to be an in-depth step by step account of how the research was carried out. This is primarily because this research does not reflect an attempt to trial an untested or controversial methodological approach to case study research. That is to say, case study research involving document analysis and interviews are already well described in practical guides written for security theorists as well as social scientists more generally. It is hoped however, that this

section communicated to others some of the practical challenges which are specific to this area of academic research.

This been said, potential shortcomings and biases of the approach adopted were still discussed at length within this chapter in the development of my analytical framework. In particular this discussion emphasised the need to validate and de-limit analytical findings with reference to available evidence. In the context of this thesis, this evidence took the form of recorded anonymous interviews (which remain on file with the Author) as well as publicly available policy documents.

Now that these issues have been addressed, we now turn to analysis of the case studies in the remaining chapters.

# Chapter Four: An Introduction to Synthetic Biology as a field of Dual-Use Concern

## 4.1 Introduction

This chapter serves several purposes which are worth briefly outlining, before introducing the chapter structure. At its most basic level this chapter is intended to introduce the reader to the dual-use concerns that stakeholders have expressed in relation to the field of synthetic biology. Naturally, this requires some form of introduction to the science, practice, institutions and technologies of which the field of synthetic biology comprises - as well as the dual-use scenarios that have been associated with aspects of the field. The second aim of this chapter is to demonstrate that the construction of dual-use issues does not just involve the embedding of objective 'scientific facts' about the practices, methods and artefacts of a field within a constructed misuse scenario. Outside of the laboratory, scientists and other stakeholders actively seek to make sense of the emerging field and this is the point at which scientific knowledge, products and institutions are conceptualised in a social context. It is these 'framings' of the science that are utilised within dual-use constructs. It is argued that these framings are based on the *episteme* (i.e. agendas and knowledge claims) of the stakeholders as well as the social norms which structure the framings of new and emerging techno-sciences within NEST assessment regimes. The concept of 'hype' is introduced as an example of this last point, which is particularly relevant when one considers that the discussions of techno-sciences are largely pre-emptive and take place in the context of the unknown and unknowable futures of emerging fields. There is also discussion of the political and institutional context in which these framings are produced, although naturally these themes are further developed in the analytical chapters. A final aim of the chapter is to begin the process of answering the questions set out in the theory and methods chapter. These questions relate to the actors, discourses and structuring conditions that are important in the examination of the process of securitization of techno-sciences.

The structure of this chapter is now outlined. In section 4.2 it is argued that emerging techno-scientific fields are understood to defy existing categorisations within predominant governance frameworks, meaning that disagreements about the scope, definition and political significance of the field have emerged. Section 4.3 introduces the underlying ways in which the field of synthetic biology has been conceptualised in policy discourse, with an emphasis on introducing the reader to the broad scope, technical aspects, practice and institutions of synthetic biology. Section 4.4 and 4.5 outline the political significance of the various framings of the field as well as how norms, in the way in which institutions in NEST assessment regimes make predictions about the future potential and future governability of technologies, are highly relevant to the understanding of how dual-use issues are constructed. Finally, in the remainder of the chapter the emergence and scope of dual-use concerns related to the field of synthetic biology are introduced.

## 4.2 The Challenge of Making Techno-Sciences 'Governable'

The increased involvement of a wide-range of stakeholders in the governance of science and technology since the end of the Second World War has created a certain fluidity in the way in which new and emerging technologies are incorporated into existing governance frameworks. In '*Designs on Nature*' Sheila Jasanoff refers to regulatory institutions' engagement with biotechnologies as 'boundary work'. Such institutions attempt to place human activity and its consequences, which are temporarily exposed by virtue of appearing novel, into finite and pragmatic conceptual categories (Jasanoff 2005, 28,230,287). Examples of these categories include: 'safe', 'risky', 'immoral', 'patentable' and 'national security threat'. In modern democracies this labelling often happens in the context of disagreements amongst interested parties such as civil society organisations, industry and branches of government, despite high levels of pre-existing institutionalisation (Stemerding, Vriend, and Walhout 2009).

In a recent report produced by researchers at the London School of Economics, it is argued that the root cause of the governance challenge synthetic biology poses, emerges from the combination of 'scientific uncertainty' and institutional 'cross-borderness '(Zhang, Marris, and Rose 2011). However, it is not the intrinsic properties of the field that lead to such problems but rather the interaction of constructions of the field with existing governance discourses.

The problem of 'scientific uncertainty' can be understood to relate to the difficulty that actors face who wish to make defensible claims about risks associated with new technologies in the absence of a legitimate risk assessment process. To explain this point further, it is not the absence of 'scientific-certainty' *per se* that allows for disagreement, but rather an absence of an agreed authoritative account of the risks associated with new and emerging technologies. Currently there is also no available funding for or active projects dedicated to risk assessment of the field of synthetic biology, suggesting that these debates are likely to continue in the foreseeable future (Synthetic Biology Project 2010, 8).

The idea of 'cross-borderness' relates to the way in which the field straddles institutional and disciplinary divides, which create difficulties for those wishing to utilise or incrementally develop upon existing governance frameworks.

Such uncertainty has led to the emergence of a collaborative assessment regime associated with the field of synthetic biology. This multi stakeholder approach to the governance of synthetic biology has certainly generated a voluminous academic and policy literature on the nature, potentials, ethics and risks of the field, which serve various political purposes in the biosafety, national security, NEST and public health domains identified in chapter two. This literature is utilized here to provide an overview of the various ways in which the field can be understood and defined. This includes reference not only to more technical aspects of the

research, but also the institutional context in which the research takes place. This precedes a discussion of the political significance of various framings of the field within NEST governance more generally as well dual-use specific governance.

### 4.3 Introducing the Cutting-Edge Field of Synthetic Biology

The term 'synthetic biology' has a long history within the biological sciences. In the work of Keller (2003), the history of the term is traced back to the work of the French biologist Stéphane Leduc at the beginning of the 20$^{th}$ century. The term was originally associated with the construction of artificial organisms which looked and behaved like natural organisms. Today however the term is used in a much broader sense (Campos 2009).The term is used to refer to a wide range of research, involving different research goals, technologies and techniques. The term is also used by a much wider range of stakeholders, including industry, civil society actors and funding bodies.

An important way of defining the field has been through comparison with more established fields of science technologies. These comparisons are made in relation to the nature of the products, the nature of the technologies and scientific techniques and approaches used as well as the institutional settings in which the research takes place. Comparisons with the field of molecular genetics and associated synthesis and screening technologies have been central to some understandings of the field, most recently demonstrated in the report on synthetic biology from the US Presidential Commission for the Study of Bioethical Issues (PCBI 2010). Within this is conception, synthetic biology is placed in the context of a heritage of genetic focused technologies (i.e. genetic engineering) which emerged in the early 1970s and continued to develop as the speed of DNA sequencing increased during the 1980s and 1990s.

However, it has also been argued that synthetic biology is not simply 'the next step' in gene focused biotechnologies. This is because of the integration of powerful computational and nanotechnology into the field as well as a broader set of conceptual tools. This has led to the claims that the field of synthetic biology operates in a different paradigm to that of earlier genetic based technologies. This is in the sense of the aims, approaches and applications of the field (Vriend 2006, 25).

Other researchers have understood synthetic biology to involve the application of engineering principles to biology. This understanding is epitomised by work associated with the BIO-bricks project and the scientist Drew Endy. Endy has argued that three ideas drawn from the field of engineering were essential if the field of synthetic biology was to reach its full potential (Endy 2005; Endy 2008). The first of these ideas is standardisation, which involves the development of a shared set of standards for the biological parts developed so that they can be utilised by other in the field. This essentially involved researchers providing detailed accounts, in a format recognisable by the rest of the community, about function, composition and environmental tolerances of given parts as they were published. The second of these ideas was abstraction. This involves the development of concepts and shared practices which allowed researchers to utilise and develop biological 'tools' as well as 'parts' without needing to fully understand the overall biological systems they were building or operating within. The final idea is decoupling which essentially involved the development of conceptual tools and practices that allowed complex biological-based engineering projects to be broken down into smaller problems which could be worked on independently and by those with the appropriate expertise (Endy 2005). Keller (2009, 35), an expert in the philosophy of biology, states in regard to Drew Endy *'I don't think I could have invented a purer exemplar, and advocate, of the engineering ideal [in the field of bioscience]'*.

While the influx of engineers into the biosciences is certainly a novel development, this does not suggest that the synthetic biology can be understood purely as collective engineering project. What is clear from the work of those who have focused upon is that the field is also influenced by epistemologies in the life sciences. This for example includes the construction of artificial models to better 'understand' life, rather than 'create' or 'mimic' life processes in the generation of new commercial applications (O'Malley et al. 2008; Keller 2009).

Such discussions of the comparability as well as the philosophical heritage of the field aside, some scholars have been inclined to take a more pragmatic approach to defining the field of synthetic biology and rather than focusing on unifying aspects, or unique qualities of the field, instead have identified various sub-fields which are operating under the label of synthetic biology. In the following section, this 'sub-fields' approach is introduced which also provides an opportunity to elaborate some slightly more 'technical' aspects of the field to the reader. This is followed by an introduction to the institutions of the field.

### 4.4 The Sub-Fields of Synthetic Biology

There are various conceivable ways to distinguish the type of research currently occurring in the field of synthetic biology. They may include the type of technologies or knowledge that are foundational to a given branch or the nature of the primary intended products (such as new scientific knowledge or biotechnologies). Another approach may be the nature of the research the field involved- for example does it involve live cell cultures, does it involve bio-chemical experiments, does it occur on a computer, or does it involve macro-level manipulation of complex organisms? Another approach could be to distinguish research branches based on the discreet teams of researchers and institutions who are operating within the field, who often at once seek to distinguish their own research and place it in the context of other work occurring within the field.

For the purposes of this chapter, the approach taken by Lam et al. (2011) is most useful in outlining the more technical aspects of synthetic biology to the reader. Within the Lam et al. approach the field is broken down into sub-fields distinguished by research approaches and purposes. This way of describing the field of synthetic biology also draws attention to the idea that work which has been referred to as 'synthetic biology' involves lines of research, technologies and institutions that pre-date the emergence of conceptions of the synthetic biology community.

### 4.4.1 DNA Circuits

The 'DNA' circuit approach within synthetic biology involves the development of standardised biological parts with predefined functions, as part of a broader project to generate numerous 'parts' that can be used together in biological-engineering projects. A key problem in this approach is overcoming biological complexity. The 'bottom-up' approach of Endy (2005, 450) tackles this complexity by breaking down tasks into a set of smaller discreet problems at different levels of biological complexity, the results of which can be combined to provide a foundational platform for the development of new applications. However the realisation of Endy's engineering-style aspirations for the field has been hampered by a series of conceptual and practical issues associated with coordinating and synthesising the various types of knowledge and expertise that are required.

To date, the field has produced technologies which have been compared to electronic components. These consist of biological, chemical and physical inputs into the biological circuits which result in predetermined outputs. This output usually involves the transcription of proteins, leading to the expression of a biological function being turned 'off' or 'on'. The most recent successes of this approach have come from the MIT IGem (Internationally genetically engineered machine project)(Goodman 2008). This project involves

undergraduate university teams developing novel organisms as part of annual competitions. Project success stories have included genetic switches that can be turned off and on by light, cell cultures that can be used to perform basic computation and addition, bio-sensors of toxic chemicals as well as biological cultures that react to light in a similar way to photographic film. Although such experiments generated one-off lab creations, they demonstrate the possibility of future wider applications of the technology. The bio-banks registry developed in this field also contains thousands of biological parts, however there is not complete or accurate information in the database for many of these parts, due partly to the WIKI style system of data entry which allows a large number of registered individuals to add parts to the system, which are in the main un-reviewed by others.[42] Despite these shortcomings, this sub-field demonstrates innovative thinking not only in its products and controversial conceptualisations of biological systems (from the perspective of traditional biologists), but also in way in which the practice of collective scientific research is conceived.

### 4.4.2 Synthetic Metabolic Pathways and Cellular Chassis

This approach involves artificial interference with the metabolic and genomic properties of cells. As in genetic modification, synthetic metabolic pathway research involves the 'splicing in' of novel DNA sequences, as well as those from other species into a cell genome. The contrast with genetic modification however is that advances in gene mapping and gene synthesis has the potential to allow for much larger metabolic pathways to be moved between cells, or designed (Lam, Godinho, and Martins 2011, 31). The most striking and popularised example of this approach has been the re-booting of cells. In these experiments an inserted genome causes the 'host' cell of a different species to express the genes of the inserted genome. In a recent experiment, the approach has led to a cell of the species *Mycoplasma*

[42] Registry is maintained online at http://partsregistry.org/Main_Page

*curriculum* being ‘changed’ into a cell of the species *mycoplasma mycoide,* following the insertion of the genome of the latter into the former. Most recently the same feat was achieved, only this time an entirely synthesised genome was used (which was based on a natural template). This sub-field has received by and far the most funding and has received public notoriety through its association with the US entrepreneur Craig Venter. Currently much of the ground-breaking research in this sub-field is occurring at the J. Craig Venter institute which has laboratories on both the East and West coast of the USA, in Rockville and San Diego respectively.[43]

It is hoped that the knowledge and technologies generated by this approach can be utilized in the design of new metabolic pathways. These pathways can then be integrated into living organisms allowing for novel cell functions. It is also hoped that simple, reliable cellular ‘chassis cells’ may be produced, which could be utilised as reliable and efficient ‘hosts’ for metabolic processes in industrial production. So far the applications of these techniques have been described as countless, specific research lines proposed include bio-fuels and the production of antibiotics.

### 4.4.3 Proto-Cell Creation

From the perspective of a scientific researcher examining the genomes and chemical reactions that take place within living cell, the complicated nature of living organisms can frustrate attempts to isolate, investigate and manipulate specific biological processes. In response, scientists have sought to engineer cells which exhibit only the most basic processes required to survive. This type of research has less immediate applications than the fields just described, but certainly offers the prospect of increased understanding of life processes, as well as the prospect of producing simple organisms which might even have the ability to

[43] For further background on the history of Venter and this institute see: (Solomon 2011, 31–149)

reproduce. This type of research is taking place in a number of university contexts. With the research that is probably best known taking place at the Szotazak Lab based at the Harvard Medical School (Lam, Godinho, and Martins 2009, 35–36). This lab focuses on the study of chemical and biological evolution. The potential industrial applications of this type of research are understood to be less immediate than the first two sub-fields, as the focus of much research is the development of more basic scientific knowledge.[44]

### 4.4.4 Unnatural Components

Within this field the aim is to create *de novo* artificial 'parts' in living organisms by attempting to manipulate or supplement the natural biological systems that produce natural 'parts' naturally within cells. The term 'parts' in essence refers to proteins, which are function-specific compounds comprising of folding the strings of amino-acids (the substances coded for in DNA). A well-known example of a protein is haemoglobin which chemically binds oxygen and carbon-dioxide in red-blood cells. Artificial proteins could be utilized within broader biochemical processes, in an industrial context, in the production of novel materials or provide more efficient ways to produce complex compounds such as those found in many pharmaceuticals. The potential utility of novel proteins has been demonstrated in theoretical computational as well as experimental research (Lam, Godinho, and Martins 2011, 35–36)

There are essentially two lines of research occurring within this sub-field which focus on different levels of the central microbiology dogma of cell function (.i.e. the causal chain of events that lie between the transcription of DNA in the cell nucleus and the production of proteins by the cell). In the first line of research, scientists are attempting to develop artificial gene-systems. This could foreseeably lead to the production of a broad range of new amino-

[44] Laboratory website available here: http://molbio.mgh.harvard.edu/szostakweb/people.html

acids and these in turn could lead to a vastly expanded range of proteins. An example project of this ilk is the ORTHOSOME[45] project based in Belgium at the Catholic University of Leuven(Lam, Godinho, and Martins 2011, 36). The second line of research essentially focuses on the generation of novel proteins, and generates these by manipulating the amino-acids found within the proteins, rather than the DNA which codes for the amino-acids. An example of this type of research is that of the Woolfson Lab, in the School Of Chemistry, Bristol. This group examines the way in which amino acid sequences effect the way in which proteins fold, which has involved manipulating and designing proteins which they claim may have applications in the broader field of synthetic biology.[46]

### 4.4.5 Synthetic Microbial Consortia

In the study of multi-cellular organisms, such as humans or mammals, bio-chemical cell-to-cell communication is understood to be essential in the regulation of bio-chemical processes. Within bacterial cell colonies made up of a single species, scientists also investigate mechanisms of 'communication' between cells. For example, the communication systems which regulate colony size in some bacterial species. This regulation usually occurs as a result of cells experiencing environmental change, which leads to some form of biochemical communication with the rest of the group to encourage a given behaviour by each cell within the collective ( i.e. slow metabolism, speed up metabolism, reproduce, die).

Another group of researchers are investigating the means to make collectives of engineered cells, each perhaps serving different functions to communicate with each other. This may enable the ability for collectives of specialised cells to perform co-ordinated collective activities that could not be performed by single cells, such as the degradation of stubborn

[45] Further Information on this project available at: ftp://ftp.cordis.europa.eu/pub/nest/docs/pathfinder_projects_2003-2006.pdf

[46] Project website: http://www.chm.bris.ac.uk/org/woolfson/index.html

environmental pollutants (Lam, Godinho, and Martins 2011, 37). An example from this sub-field of research is a project of Dr. Jingjing Sun at the Weisse Lab at MIT.[47] This research involves manipulating the metabolic systems found within yeast that lead to cells commutating the messages that encourage cells within the colony to 'commit suicide' (which in nature is used when the colony needs to reduce its numbers because of environmental pressures).

### 4.5 The Funding and Practice of Synthetic Biology Research

While a generally agreed unifying definition of the field of synthetic biology have not been forthcoming, funding and institutional support of the diverse sub-fields of research have been provided under the label of synthetic biology since at least 2005. This financial incentive has motivated new forms of collaboration between discreet disciplines under this banner. The result is a patch-work of collaboration between research teams and institutions with overlapping, but often distinct interests and aspirations (Molyneux-Hodgson and Meyer 2009). There are discreet funding environments for the field in the US and the UK which are now outlined.

Within the US the main sources of investment have been the Department of Energy (DOE) as well as the National Institutes of Health (NIH), the National Science Foundation (NSF) and the Department of Agriculture (DoA), totalling around $430 million between 2005-2010 (Zhang, Marris, and Rose 2011, 11).The Defence Advanced Research Agency (DARPA) also announced an investment of $30 million in 2011.[48] This has also been supplemented with private investment mainly in applied projects (Synthetic Biology Project 2010), for example Synthetic Genomics Inc. have reportedly invested approximately £30 million since 2005 and

[47] Project website: http://groups.csail.mit.edu/synbio/people/jingjing-sun/

[48] Grant details available at http://www.grants.gov/search/search.do?mode=VIEW&oppId=119953

have collaborated with Exxon Mobil, who have reportedly invested approximately $600 million (Howell 2009). Another major contributor to the field has been Amyris who have reportedly raised around $224 million. Most private investment has focused on the development of biofuels (Fitzpatrick Dimond 2010).

Collectively, US based synthetic biology is understood to involve over 180 institutions (Synthetic Biology Project 2010, 3).These institutions include universities, private research intuitions as well as National Laboratories. Within the US there is also over 24 gene synthesis companies, and the US has been described as initiating the industrialisation of the field (Synthetic Biology Project 2010, 4).

In contrast, within the UK, state investment into the field lags behind the US with estimations ranging between £20 million and £53 million between 2005 and 2010. There has also been a recent collaborative investment of £2.4 million from DSTL, BBSRC, EPSRC and the MRC. In both the UK and the US up to 5% of public budgets were allocated for engagement with social and ethical issues in the field. Such activities also seemed to contribute to the emergence of critical attention from CSOs in the US. This has also been reflected in the involvement of a number of social and political scientists as well as the production of a range grey literature (Zhang, Marris, and Rose 2011, 12).

A major aspect of the organisation in the UK of the field of synthetic biology has been seven UK networks which were funded over a three-year period between 2008 and 2011 by the BBSRC, EPSRC, ESRC, and AHRC.[49] These have involved a number of national and international conferences. In the US, Drew Endy of the Bio-Bricks Foundation initiated a series of international conferences. The first, second and fifth of these conferences took place

[49] Funding call available at :http://www.bbsrc.ac.uk/funding/opportunities/2007/synthetic-biology.aspx

in the US (2004 and 2006, 2011), the third took place in Europe (2007), the fourth in China (2008) and the sixth conference took place in the UK in 2013.

The field of synthetic biology is also being institutionalised further with the emergence of post-graduate courses that focus in the field. In the UK, for example, LSE as well as the University of Edinburgh offer a *Masters by Research in Systems and Synthetic Biology*. Added to this, SyntheticBiology.org associated with the open wetware Bio-Bricks Project, identified over ten US institutions that supported graduate study in the field.[50]

The growth of the amateur community

Since 2003 there has been discussion of an emerging amateur community. This community consists primarily of a handful of small organisations (National Science Advisory Board for Biosecurity 2011, 6). One of these organisations is DIYbio, an organisation which is '*dedicated to making biology an accessible pursuit for citizen scientists, amateur biologists and biological engineers…*'[51] a second is the glibly named *Biocurious* who state that '*We believe that innovations in biology should be accessible, affordable, and open to everyone'* [52] a third example is Genspace who define themselves as '*a non-profit organization dedicated to promoting citizen science and access to biotechnology.'*[53] Another group which has emerged within the UK is Manchester DIYbio which has developed in collaboration with Manchester Metropolitan University - which is designed to encourage wider participation in biological research.[54]

50 Data available fro: http://syntheticbiology.org/Graduate.html
51 Website:http://diybio.org/
52 Website: http://biocurious.org/
53 Website:http://genspace.org/
54 Website: http://madlab.org.uk/content/diy-biology-manchester-gains-funding-for-innovative-new-%E2%80%9Ccitizen-science%E2%80%9D-partnership/

The actual capabilities of these groups remain comparable to high school laboratories (Ledford 2010). However, pioneers such as Carlson have envisaged a future in which amateur communities play a role in replicating or generating technologies as well as producing products such as pharmaceuticals (Aldrich, Newcomb, and Carlson 2008). The relationship between the amateur community and regulatory institutions, as well as the relationship between the amateur community and the field of synthetic biology remains contested in both a UK and US context and the significance is examined in later chapters.

### 4.6 The Politics of 'Making Sense' of Synthetic biology

The way in which actors and publics make sense of emerging techno-scientific fields is a complex process. The various framings of synthetic biology available to actors, generated by think-tanks, horizon scanning exercises, public discussions and indeed science fiction, can be used to serve political purposes such as mobilising and coordinating action as well as legitimising activities. The most notable example in synthetic biology is the emotive depiction of the field of synthetic biology by civil society groups such as '*Genetic Modification on Steroids*'- a metaphor designed to elicit a revival of long-standing debates about risk comparable to that seen in relation to genetic modification technologies.[55] In a situation where several actors are in a position to articulate a conception of the field's future and significance, it is unsurprising that different conceptions of the field are prevalent. Added to this, the 'cross-border' and interdisciplinary nature of synthetic biology also make this field particularly malleable within public discourse in contrast to 'established' fields, which are understood to have more clear-cut, institutional and technological heritages. This leads to the observation that despite the 'revolutionary' framing of synthetic biology, promissory

[55] A phrase predominantly associated with the ETC civil society Group, website: http://www.etcgroup.org/fr/node/602

discussions are actually dependent on the identification of a wide range of analogous-established and familiar technologies and scientific fields.

Such analogies have certainly been forth-coming (in particular computing and electronics); however the explanatory and predictive strength of such analogies is always limited. One of the earliest comparisons to electronics was made by Carlson (2003; 2011) which focused on polynucleotide synthesis technologies as a primary enabler to the field. In his work he predicted that the cost of polynucleotide production per base could reduce exponentially, as had happened in the semi-conductor industry. Such reduction in cost, was also linked to increased speeds of production. This exponential change was understood to be a the result of a feedback cycle involving the decreasing cost of polynucleotide sequences and the increasing availability and distribution of ever more powerful gene focused technologies.

The focus on polynucleotide synthesis as a key driving force in the development of the field risks over-emphasising the role of this enabling technology and ignoring other limiting factors such as computational capacities, financial resources and availability of the appropriate expertise and new techniques. Similar arguments are made in relation to computing technology analogies. These predictions for example seem to disagree about the role of amateurs in the emergence of the field. Advocates of higher contributions point to the amateur computer programmers of the 1970s (Schmidt 2008). Conversely, others have tended to point to the role of large well-funded projects and institutionalised expertise have played in the development of biotechnologies (Aldrich, Newcomb, and Carlson 2008)

The take home lesson from such observations is that while actors may make claims about the development of the field and emergence of applications, such claims are based on a wide range of assumptions. There also seem to be motivations for those advocating fields to construct the field through comparisons with other fields despite the obvious limitations of

these approaches. This applies to both making claims about the potential for the field and contesting the governability and risks associated with the field.[56] In essence, as a consequence of the anticipatory nature of debates within NEST-assessment regimes, the absence of agreed definitions of the field are both a cause and result of political disagreement about risks and potentials of the field. As Kaiser et al. have already highlighted, these debates make unknowable futures the subject of debates and reflect actors' conceptions of the ideal role of science and technology in society (Kaiser, Maasen, and Kurath 2010a).

### 4.7 The Politics of Science Hype: Implications for Dual-Use Scenario Construction

It has just been argued that the risks and potentials of synthetic biology are essentially contested within the policy community, and that this is reflected in the way in which the field is conceptualised and communicated by various stakeholders. This highlights the way in which claims about science are not the same as scientific claims and are likely to be contested as freely as any other aspect of a potential dual-use scenario. This raises interesting questions about how science is understood and communicated in relation to the governance of the dual-use issue and what effects this has on the securitisation potential of the field. The concept of 'hype' is now introduced as a means to show the way in which a general trend within NEST governance is highly applicable to understanding how aspects of science and technology of concern are identified in the dual-use pre-assessment regime.

An interesting question is the policy impact of the period of hype that follows the initial identification of a trigger technology in the early phases of techno-science emergence (Mampuys and Brom 2010). This period of hype tends to involve very optimistic predictions

[56] This argument has already been made well in relation to nano-technology in Kaiser, Maasen, and Kurath (2010b)

about the speed of new application emerging, as well as the societal impact of these applications. If the trigger within the field of synthetic biology is understood to be gene-synthesis then this hype cycle began as early as 2002, with the identification of gene synthesis technologies as having a revolutionary impact by individuals such as Carlson. This 'hype' reached its peak in the period between 2006-2010, at which point Mampuys and Brom (2010) have identified evidence of scientific articles which down-play the potential of the field, signifying the downturn in expectations of the field.

Coincidently it the time period in which academics and commentators were likely to be 'over-valuing' the revolutionary potential of synthetic biology and the speed at which applications would emerge, coincided with the elevated levels of bioterror concern in 2002, following the US Anthrax attacks. The broader field of synthetic biology, already on many security institutions' radars due to concerns about polynucleotide synthesis, may momentarily have provided a fertile field for the generation or dual-use issues in the minds of many of those conscious of the threat posed by bioterrorism. Vogel (2008a) has already identified the role of '*group-see dynamics*' within intelligence communities who examine bioterrorism threats can lead to the 'overvaluation' of the likeliness and seriousness of potential threats, and uncritical acceptance of threat scenarios within that community. Such claims are also made by Koblentz (2010, 98) who argues that in such situations '*extreme worst-case assumptions is the rul*e'. These claims are not made here in an evaluative sense, or meant to characterise these constructions as irrational or as ungrounded in fact. This idea is instead raised to make the point that hype combined with an increased bioterror imagination seem to have allowed for the generation of dual-use issues related to the field of synthetic biology among security policy communities in a way that was unprecedented historically.

Such hype can potentially serve as a valuable rhetorical commodity as actors in the various domains of dual-use governance seek to mobilize and coordinate in pursuit of policy objective (such as pre-emptive science and technology regulation), or else in raising a specific issue on agendas (such as the absence of convincing science and technology review processes at the BTWC at international level).

It currently remains unclear within the existing literature as to whether the same levels of technology hype have been experienced within the UK and US, as well as the way in which this has affected dual-use governance. However, this may be an important factor in explaining the emergence of more fantastical dual-use scenarios in the governance discourse.

To sum up, the dual-use concerns involve assumptions about the current understandings and future visions of science and technology, as well as claims about the contexts and scenarios in which the field could be misuses.

### 4.8 Overview of Dual-use Synthetic Biology Concerns

Since at least 2004 (Tucker and Zilinskas 2006) dual-use discussions related to synthetic biology have referred to bioterrorist threats associated with synthetic genomics, military (including biodefensive) interest in the field as well as the potential diffusion of knowledge and technologies related to this field . The key concepts and arguments that have been central to discussion of dual-use aspects of synthetic biology over recent years are now introduced.

#### 4.8.1 Synthetic Biology and Bioterrorism

Polynucleotide synthesis was the earliest and most prominent aspect of the field of synthetic biology to be problematised as a source as ‘dual-use’ concern (Kelle 2009a). The earliest document identified within the literature was produced in 2003 by a small network of

concerned scientists (known as the Sunshine Project). The document referred to the prospect of the synthesis of classic warfare agents, as well as novel agents, with a focus on the consequence of state investment in bio-defensive research for non-proliferation and inter-state arms control (Sunshine Project 2003).

This was followed in 2004 by the publication of a non-proliferation proposal by George Church (Church 2004), a leading scientists in gene sequencing, at the Harvard Medical School. This document considered the option *'of setting up a clearing house with oversight assigned to one or more of Homeland Security or the FBI'.* The document made two suggestions. First, it suggested that oligonucleotide (oligo) sequence[57] orders should be screened for similarity to select-agent pathogens. The paper also suggested that all use of reagents and oligos '*could be automatically tracked and accountable (as is done for nuclear regulations) '*. Church also discussed the potential for the *de novo* synthesis of select-agents by terrorists utilising current science and technology.

Since the Church proposal, attention has been given to the idea of licensing or monitoring of polynucleotide synthesisers as a means to reduce proliferation potential (Nouri and Chyba 2009). However, this approach is usually discussed in terms of the expense and hindrance such measures could cause (Garfinkel et al. 2007). There have also been proposals which have focused on engineering monitoring or safeguards into new DNA synthesisers.(Nouri and Chyba 2009).

In recent years, the most dual-use polynucleotide synthesis discussion has focused on the development of synthesis industry screening practices. These have been designed to prevent terrorists from being able to buy dangerous sequences from providers. Currently there are

[57] Oligos are short chains of single stranded DNA molecules ( or RNA) which are short ( less than 200bp) and have a range of applications within research.

understood to be three competing voluntary standards, two of which come from industry associations and the other from the US government. A concern on the horizon within this literature is the development of polynucleotide synthesis technologies in states outside of the Australia Group as well as the ability of scientific developments to undermine polynucleotide sequence focused screening (Schmidt and Giersch 2011). This for example includes the prospect that faster, cheaper and more user-friendly synthesis technologies will potentially mean that many companies will choose to have an in-house synthesis capacity, rather than being reliant on synthesis providers.

### 4.8.2 Synthetic Biology and Bio-Warfare

The recent interest of military research institutions such as DARPA and DSTL also seem likely to raise concerns within the arms control and national security communities about increasing perceived military utility of the field, which may undermine the norm against biological and indeed chemical weapons. Conversely, it has been argued by members of these communities as well as the scientific community, that pursuing research in this field is essential to developing bio-defensive and bio-security systems against potential threats (Maurer, Lucas, and Terrell 2006, 7). However these responsive in themselves, particularly research which would involve working with classic warfare agents, would potentially generate concerns about biodefensive research crossing the line into offensive research (as discussed in chapter two). This then suggests the need for oversight mechanisms beyond that of the synthetic biology community (See for example, Weir and Selgelid 2009) .

Kelle (2009a) has argued that current debates focused on the threat of bioterrorism and community self-governance neglect the threat of state-level biological weapons. Within his work the issue is understood to be a problem that involves the threat posed by the possible acquisition of dangerous technologies and knowledge by terrorists, as well as the threat posed

by offensive weapon programmes. This is reflected in his call for a holistic approach to the governance of the field which includes sub-national, national and international approaches to the governance of biosecurity of the field. This looks beyond existing policy and proposals directed at the threat of terrorism; considering the future long-term international security implications of the field, including those related to state funded bio-defence research. He also argues that the dual-use issue involves a broader aspect of the field of synthetic biology than synthetic genomics (Kelle 2009b). Within this conception, the scientific community, national governments or gene synthesis industry are not in a position to develop and implement responses to the dual-use issue alone.

Within the analytical chapters, the extent to which this challenge has been understood and taken up at national level is assessed.

### 4.8.3 Synthetic Biology and the Threat of Diffusion

Since at least the early 2000s (Carlson 2003), there has been attention given to the idea that the de-skilling agendas of both institutional biology, as well as the amateur community have implications for national security and international arms control. This has been in the sense that the field can be understood to facilitated those without biological training to deal with potentially dangerous organisms. This aspect of the issue has often been discussed in terms of biosafety practices (Schmidt 2008, 2). It has also been argued that the de-skilling agenda has the potential to undermine both national and international controls on biological weapons (Tucker 2011). As Schmidt also highlights in relation to the oversight of gene-synthesises, the development of polynucleotide synthesis facilitates in countries outside of the Australia group could be understood to challenge the existing regulatory system (Schmidt and Giersch 2011).

Aspects of the amateur community have also been identified as a source of dual-use concern (Markus Schmidt 2008; Wolinsky 2009; Jefferson 2013). The focus of much discussion has been on the political motivations of groups involved in the amateur synthetic biology community which often exhibit anti-establishment characteristics (Delfanti 2011). There are fears that sub-cultures may develop within these groups that seek to develop weapons - as can be observed in some computer-hacking communities. So far, publicly known policy proposals have related to outreach and the development of responsibility within these communities, however amendments to the patent system have also been considered as a means to encourage the amateur community to maintain biosecurity compliance, as well as to monitor developments within the field (Gorman 2011).

### 4.9 Conclusion: Securitization, Risk and the False Dichotomy of Promise and Peril

In chapter one it became clear that while it is possible to study the dual-use issue as an 'ethical dilemma' facing the scientific community, that this is a rather myopic approach if one wishes to fully appreciate the various ways in which the issue has been constructed as a governable problem by policy-making communities. Dual-use governance has involved a wider set of value judgements, as well the issues of ambiguity and complexity. Further to this it was argued that the broad range of governance activities that have emerged in response to the dual-use issue exist as part of a broader governance regime directed at the issue. What remained unclear however was the extent to which activities within the four domains reflected what one would expect to see in a systemic risk governance regime.

In chapter two it was argued that security politics is still a suitable departure point in making sense of the politics and practices of dual-use governance. The UK and US are intriguing comparative studies as governance of dual-use issues within these states are still

conceptualised along security/ non-security axis by many academics and policy-makers. Following this, a theory of securitisation was introduced which could adequately incorporate agency, discursive and histo-political factors in the study of dual-use governance. However it became clear that there was a requirement to reflect on how to study the securitisation of techno-sciences in the absence of existing literature on this issue.

In chapter 3, the techno-scientific field of synthetic biology was introduced as a source of dual-use concern. Within this chapter it became clear that scientific practices, technologies and knowledge, were not the focal point of analysis; but rather the framing of these social artefacts, which are essential components of dual-use misuse scenarios. This last point emphasises that dual-use issues are not simply constructions that emerge out of the existing national security *episteme*, but instead the result of the interactions of framings of (usually) civilian newly-emerging science and technology and pre-existing national security pre-occupations, such as mass casualty terrorism. Further to this, it was also argued that the emergence and ascribed significance of such scenarios may be affected by a wide range of histo-political factors. The concept of hype was used to emphasise this point.

The observation that dual-use problems do not 'appear' but are made, inevitably leads to questions about the nature of the overall political process that has created dual-use problems and the associated governance regimes in the field of synthetic biology. This essentially involves addressing questions related to the 'subject' or 'scope' of governance ( i.e. which specific aspects of synthetic biology are subject to dual-use governance) as well as the '*politics*' and '*practice*' of governance (i.e. how are policies generated, what nature of policies have been implemented?). This also leads to questions about emerging overall approaches to the governance of dual-use issues related to cutting-edge aspects of synthetic

biology in national contexts. In the following sections these questions are addressed in relation to two national case studies.

# Chapter Five: The Politics and Practice of Dual-Use Governance in the US

## 5.1 Introduction

In this chapter there is analysis of the governance dual-use aspects of synthetic biology in a US context. The way in which analysis has been carved up reflects the discreet policy-generating forums and processes which have given rise to dual-use governance activities directed at the field of synthetic biology. In the first section there is discussion of how the concept of dual-use techno-science emerged on US agendas. This involves introducing key institutions in the development of dual-use governance, specifically the NSABB and SynBERC. In the sections that follow, there is discussion of the governance of dual-use technology and dual-research in a US context (the discussion of technology rather than research first reflects the chronology of major developments in relation to these issue areas). In the final section, there is an analysis of the recommendations of the Presidential Commission for the study of Bioethical Issues (PCBI) (PCBI 2010), as well as the prospect of a new style of dual-use politics directed at the techno-science of synthetic biology, with reference to recent developments at SynBERC

## 5.2 Early Biosecurity Initiatives in the Emerging Synthetic Biology Community 2003-2005

If aspects of the US government were ever going to react drastically to the threat posed by biotechnology, the biggest window of opportunity in the previous decade within the political stream was the period 2002-2005. This is for several reasons. First, as Maurer states during this period there was a

> *'… Crisis atmosphere [which] predictably led to various Executive Branch responses… Such concerns also occurred in the context of the recent tightening of biosafety and vetting measures on individuals working with select-agents'* (Maurer 2011, 1395).

As Maurer has also pointed out the establishment of the NSABB in 2004 had also generated the expectation that the US government would take some form of action (Maurer 2011, 1397).

This suggests that there were appropriate facilitating conditions for the US executive to formulate and execute a primary securitisation move related to polynucleotide synthesis if the political will and capability had been there. Added to this, George Church, a publicly prominent and widely respected scientist[58] had formulated and actively advocated a policy proposal (Church 2004) which discussed the prospect of national security style controls which would utilise systems analogous to drugs control and nuclear counter-proliferation.[59] The proposal also gave the US security institutions a prominent role (he suggested collaboration between the CDC, DHS, and FBI).[60] Yet despite this, policy initiatives were not forthcoming from the US government. It wouldn't be until 2007 that the US government would take any concrete action, when a task force was convened (under the auspices of the HHS, rather than the FBI or DHS) to begin the process of developing federal guidelines in relation gene-synthesis technology.

George Church's proposals were discussed at the first synthetic biology conference held in 2004. These discussions reflected the emergence of a political synthetic biology community which was not only discussing dual-use issues but aspiring to engage with governance (Carlson 2005; Maurer, Lucas, and Terrell 2006). In 2005, following discussions at SB.1, Church wrote an article in *Nature* which contributed to expectations that biosecurity actions would be taken at S.B2.0 (George Church 2005). With regard to synthesis technologies, his

58 George Church was a pioneer in the emergence of DNA sequencing and synthesis technology and remains closely involved with the field of Synthetic biology today.

59 This proposal came after gene synthesis technologies were implicated in dual-use concerns in relation to the synthesis of viruses around 2003.

60 Aspect of the CIA were interested in this issue at around this time, see (CIA 2003)

report focused on the possibility of surveillance and material controls. His suggested approach was in stark contrast to the perspectives of some aspects of the scientific community at the time. For example, following the SB.1 Robert Carlson stated that;

> '*Not for the first time in this circle did I hear suggestions of licensing for scientists and of strict controls on the distribution of technology and reagents. But such measures are not likely to be effective. Worse, they will instil a false sense of security.*'(Carlson 2005)

Such sentiments would ultimately motivate counter-proposals from within the academic community and gene-synthesis industry who would go as far as stating publicly in 2006 that Church's initial proposals were '*impractical*'(Bugel et al. 2006). As time went on then, the implementation of the Church's initial proposals looked increasingly unlikely as competing visions of dual-use governance, with a broader[61] appeal in the emerging scientific community, began to take shape.

As early as 2003, Drew Endy had raised the idea that academic scientists could place pressure upon industry to implement screening standards (Maurer 2011, 1426). Fresh impetus was given to his perspective in November 2005 when an alarming article in the New Scientist entitled '*your bioweapon is in the post'* (Aldhous 2005) raised the prospect to the public that terrorists might order from these service providers. This in itself was worrying for concerned aspects of the community, but also heralded mounting public pressure on the government to act for some observers. Just 3 days later, it was reported in the New Scientist that Endy's Lab would:

> '*…only do business with companies that operate transparent procedures for screening gene-synthesis orders for potential bioweapons. If other researchers follow suit, rather than simply placing orders on the basis of cost or speed of delivery, the*

[61] Church's proposals would have likely to have created an extra set of responsibilities for the scientific community (probably biosafety officers or Primary investigator) to implement tracking and monitoring systems within ( and probably during transportation to and from) their labs of relatively basic and common materials and technologies. Naturally, some vocal aspects ot he scientific community were averse to such a burden.

*whole industry would be forced into adopting tougher standards'*(New Scientist 2005).

However, in the following year, politics conspired against leading members of the emerging synthetic biology vanguard who were seeking to develop and implement self-governance mechanisms. This resistance would not only stem from the anti-terrorism domain; if anything it would appear that institutions such as the FBI were supportive of industry and academic self-governance initiatives at this time.[62] Instead, it was divisions within the policy stream as well as the political landscape of the US NEST domain which would frustrate community attempts in 2006 to implement policy directed at dual-use issues.

Events in this early era are important understanding the politics of US dual-use governance; this is in four senses. First, George. W Bush-era homeland security politics is often characterised as involving knee-jerk and draconian responses – however the Federal response to biosecurity issues in this era were not in fact not that straightforward. While the state has taken drastic action and taken the lead on issues on biodefense - there has been less willingness to take action in relation to dual-use issues. If one were to assume that the government had indeed wanted to take urgent action in dealing with the threat posed by polynucleotide synthesis, it is likely that the Church proposal would have been used in a securitisation move for this purpose - perhaps resulting in a closed policy development process directed by the US executive. This action was not taken however. In fact what followed was that the US executive adopted a 'wait and see' approach in the period between 2003-2006[63] as various state and non-state expert panels grappled with the issue. Second, the hunt for technical science-based solutions to dual-use issue - through either better screening

[62] This is reflected in the involvement of the FBI in the first major self-governance proposal which followed S.B 2.0 as part of tripwire initiative FBI website http://www.fbi.gov/about-us/investigate/terrorism/wmd/key-programs

[63] During this time the NSABB, the primary source of such guidance, had been slow to get started. Evidence of this in (Gerald L Epstein 2012, 22)

or through engineering safeguards into technology would continue to be prominent within the US discourse. Church's early efforts to launch policy initiative also reveal competing conceptions of what constitutes desirable dual-use governance within the synthetic biology community, as well as a the willingness of this community to engage with such discussion and even action. Finally, the absence of support for this early initiative reveals the potential for mismatch between more forward-looking initiatives stemming from the immediate agora around the field and the more slow-moving and pragmatic federal institutions. These processes are now examined in further detail.

### 5.3 Dual-Use on the NEST Agenda

In the following two subsections, two institutions which are key to understanding the politics which surrounds the governance of dual-use synthetic biology are introduced. The first of these is SynBERC,[64] a major federally funded synthetic biology research centre. This centre has a well-established tradition of collaboration between synthetic biologists and those concerned with governance issues. The second is the NSABB, which is a federally established advisory body tasked with examining dual-use issues, including those associated with the field of synthetic biology.

#### 5.3.1 SynBERC: Dual-Use Techno-Science on the Community Agenda

After the first synthetic biology conference of 2004[65] a group of engineers and life scientists from US institutions proposed the establishment of a collaborative project (Synthetic biology Engineering Research Centre or SynBERC). It was intended that this centre would enable the coordination of research activities across these institutions. The goals and means, as well as some of the technical and conceptual hurdles of such collaboration had already been

[64] Website: http://synberc.org/
[65] Held in Cambridge MA 2004.

discussed by this time at S.B1.[66] A funding application was made to the NSF, who financed the project from summer 2006, on the proviso that the project would include a social implication element, particularly in light of terrorism concerns related to the field. Since this time a series of scholar have served as leads of the ethical component of this project - which has been a turbulent institution for social scientists to work in. For only a matter of weeks, the post was held by Stephen Maurer, a scholar based in the Berkley School of Public Policy, he was replaced at the end of summer 2006 by Paul Rabinow and Kenneth Oye. Rabinow was an anthropologist working at Berkley and Oye a political scientists working at MIT. At the End of 2010 Rabinow was removed as the head of the Human Practices thrust and replaced, by prominent synthetic biologist Drew Endy. This followed disagreements over the purpose and outputs of the thrust.

Since at least 2006 the aspirational 'up-stream' policy initiatives within this institution have continually shown faith in the idea that security considerations could be engineered into the synthetic biology innovation processes. This was demonstrated as early as 2006, when Stephen Maurer secured funding from the Carnegie Corporation of New York and MacArthur Foundations for a collaborative project which was designed to '*study and facilitate community action on issues of concern to the worldwide synthetic biology community*' (Maurer, Lucas, and Terrell 2006). The research project, involving interviews with experts; coordination with other institutions and working groups as well as two public meetings, was designed to be the basis for eventual community-based action. Initially, things started well as an exercise in the delineating self-governance policy options. A report produced a few months before S.B 2.0 suggested a set of policy options to be considered by the scientific community at the forthcoming conference. The report asserted that:

[66] For example, the first SB conference (2004) included tutorials that described how to establish and run a registry of standard biological parts as well as tutorials for educators who wished to teach integrated biological systems engineering. http://openwetware.org/images/7/79/SB1.0_overview.pdf .

> '*synthetic biologists share a deep understanding of the biosafety/biosecurity problem and – in some cases – emerging consensus about what can and should be done to manage it. Many options can be implemented through community self-governance without outside intervention'*. (Maurer, Lucas, and Terrell, 1)

The advocacy for self-governance was tempered with the statement that:

> '*Community self-governance provides a realistic and potentially powerful complement or alternative to regulation, legislation, treaties, and other interventions by outside entities.* (Maurer, Lucas, and Terrell 2006, 4)

The report also confidently reassured to those looking on that policy proposals were the result of a consultation with the scientific communities through interviews which had set out to learn '*what members believe, want, and are prepared to vote for'* and that the policy proposals were derived *'from consent'* (Maurer, Lucas, and Terrell 2006, 5).

It was intended that the vote would take place publicly at the SB 2.0 and involve scientists within the community. The resolutions within this document that directly addressed polynucleotide synthesis technologies included an insistence that the academic community only deal with gene-synthesis companies which had adopted best-practice screening procedures by a given date and the engagement of scientists in research on screening to further facilitate the implementation of these best practices. The proposals also addressed research. This included the appropriation of the synthetic biology community as both experts in dual-use governance and implementers of security policy - the report states, for example, that

> '*Six years of almost continuous discussion have given synthetic biologists a solid understanding of biosafety/biosecurity risks and the available possible policy instruments for reducing them*' (Maurer, Lucas, and Terrell 2006, 25).

The report also gave the scientific community a central role in the development of policies to prevent and mitigate the risk of the misuse of developments within the field. Other modest initiatives not in keeping with existing risk governance systems were also suggested, such as: the 'biosecurity hotline'; education of students about dual-use issues; outreach to the

emerging amateur bio-hacking community as well as the incorporation of dual-use expertise into existing bioethics/ biosafety review was also suggested.

Various factors would conspire to undermine this initial experiment. Some factors were internal to the SynBERC Project - members of the other research thrusts on the SynBERC projects began private discussions which resulted in Maurer's proposal been pulled '*at the very last moment* by *Keasling and his colleagues*'(Rabinow and Bennett 2012, 18). Maurer suggests that there were several reasons that members of the organising group pulled the proposal for the agenda;

> '*Some needed more time to think about the ideas. Others were concerned that the conference needed a constitution before it could vote, or that a vote might be divisive. Some participants hesitated out of respect for the fierce opposition of activists'*(Maurer and Zoloth 2007, 17).

These activists, headed by the ETC group, publicly criticised the 'Asilomar-style approach' suggested by Maurer's' group on the basis that it was undemocratic and represented a pro-science agenda. A further reason given for the Berkley project not achieving its original aims was that the initiative was trumped by the announcement of a Sloan Foundation funded project involving the Craig. J .Venter Institute which would also discuss options for federal oversight. This was to be published after the SB2.0 (Maurer 2011, 1398–1399). Regardless of the causes, SB2.0 did not include a community-wide vote on the implementation of biosecurity actions. Added to this, Maurer highlights the incorporation of Civil Society Groups such as the ETC at the SB3.0 and SB4.0 events would block the prospect of any such action in the future (S. Maurer 2011, 1429). However, despite the fact this project did not achieve its primary aims, other outputs from this project including draft reports and an online resolution were utilized in future reports and would influence future initiatives. The extent of this influence will be outlined in later sections of analysis.

### 5.3.2 The NSABB: Dual-Use Techno-Science on the Federal Agenda

In order to understand federal policy on dual-aspect of synthetic biology it is essential to examine the role of the US federal advisory board on dual-use research which was established in 2004 following the recommendations of the Fink report (National Research Council and Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology 2004) (see chapter one). The report recommended the establishment of an advisory board that would be located within the Department of Health and Human Services (HHS). Since its establishment the board has produced a series of recommendations for government on specific dual-use issues and dual-use policies and has also provided advice on specific dual-use cases which have received public attention.

As a federal advisory body, the charge of the NSABB is codified in a charter. This charter also sets the terms on which NSABB provides advice to the government. Because this committee is a federal advisory body it is also required by law to keep public records of its finances and meeting. The large documentary footprint of the NSABB belies the fact that the institution actually operates on a modest budget of around $541,120 per year (Secretary of Health and Human Services 2012, 2). The NSABB has no independent full-time staff. Instead a designated federal officer assigned by the NIH is in charge of: approving and calling NSABB meetings, preparing and approving all meeting agendas, attending all committee and subcommittee meetings, adjourning any meetings when it is determined to be in the public interest and chairing meetings when directed by senior officials. The NSABB committee comprises of up to 25 voting members, plus other invited experts who meet intermittently. The work package of the NSABB was broken up between a series of working groups.[67] One of these working groups (The Synthetic Genomics working group) focused specifically on the

[67] By the end 2006, there were six working groups;
Dual Use Criteria Working Group, Communications Working Group
Codes of Conduct Working Group Synthetic Genomics Working Group
International Working Group and the Dual-use research oversight working group.

issue of polynucleotide synthesis technology. The working group, under the aegis, produced an influential report (NSABB 2010a) which would serve to frame future federal responses.

The role of the NSABB in dual-use governance has been subject of contestation among academics, commentators as well as policy-makers. During an interview, one senior individual closely involved with the Fink report drafting process stated that that the role of the NSABB '*depend[ed] on who you ask.'*[68] The official role served by the NSABB is to:

> '*provide advice on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community to foster continued rapid progress in public health and agricultural research*'. (Secretary of Health and Human Services 2012)

In practice, the actual remit of the NSABB has been quite fluid, with alterations in the boards charges between 2005 and 2012. This may partly represent the completion of work programmes but also reflects changes in the understood role of the NSABB. A snap-shot of the understood role of the NSABB when Genomics work programme was established, is provided by the executive director of the NSABB who outlined 12 charges.[69] This list demonstrates that there is a potent range of roles that the NSABB could have played in the

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68 Interview with senior National Academy of Science policy shaper: On file with Author

69 Develop criteria for identifying dual use research and research results; Develop guidelines for oversight of dual use research, including guidelines for risk/benefit analyses; advise on national policies governing local review and approval for dual use research, including guidelines for case-by-case review and approval by Institutional Biosafety Committees (IBCs);Advise on criteria and processes for referral of classes of research or specific experiments by IBCs to NSABB; Review/provide guidance on specific experiments that exemplify significant or complex permutation or represent a new category of dual use research; Respond to research institutions' requests for interpretation and application of guidelines to specific proposals that have been denied by an IBC; Provide recommendations regarding the development of a code of conduct for scientists and laboratory workers for adoption by professional societies and institutions engaged in life sciences research; Provide recommendations on the development of mandatory programs for education and training in biosecurity for all scientists and laboratory workers at federally funded institutions; Advise on national policies for publication, communication, and dissemination of dual use research methodologies and results; Provide recommendations regarding strategies for coordinated international oversight of dual use biological research; Advise on national policies for conduct of dual use research, including strategies to address national security concerns while fostering rapid progress in life sciences research Address other issues as directed by the Secretary of HHS. From a presentation given by Thomas Holohan (then Exectutive Director of the NSABB) at the NSABB inaugural meeting June 30-July 1st 2005, Bethesda. http://osp.od.nih.gov/office-biotechnology-activities/event/2005-06-30-160000-2005-07-01-160000/nsabb-first-meeting

governance of dual-use aspects of synthetic biology. It is worth briefly characterising these roles in the context of the analytical framework.

The first set of roles relate to the impact of the NSABB in the life cycle of specific policies. In a meeting report from 2005, the executive director at the time indicates that the NSABB roles were to

> '*identify and analyse dual use research issues, facilitate coordination in the development of Federal policies on dual use research, participate in the implementation and interpretation of the Federal guidelines for dual use research, and develop training and education programs for IBCs'* (NSABB 2005a, 5–7).

This suggests a broad remit in the linear policy development process, ranging from issue identification and policy development and selection, through to policy evaluation. The understood role of the NSABB at this time would also look to include many of the roles often ascribed to policy entrepreneurs including: advocating new ideas and developing proposals, defining and reframing problems and specifying policy alternatives. Added to this there is also evidence to support the argument that the NSABB at this time was involved in other roles typically ascribed to policy entrepreneurs. The first is the mobilization of public opinion, the importance of public opinion a common theme at the inaugural NSABB meeting, with references made to the NSABB can help maintain public trust in federally-funded science (NSABB 2005b, 8,11,164). This was also reflected in concerns about public misperception of the dual-use issue, with some members of the NSABB claiming that the '*public must be educated on the complexity of dual use issues'* (NSABB 2005a, 7). Another role envisioned for the NSABB in 2005 was the idea of brokering ideas among the various communities and building collaborative relationships between stakeholders. This is reflected in an interview with an expert involved with the Fink report drafting process, as well as a regular attendee at early NSABB meetings: '*Because we thought, the committee thought you*

*would <u>really</u> need a source of continuous engagement between the science community and the security community'*. This was in as far as identifying and responding to dual-use issues.[70] Another role the NSABB could be expected to play is also setting the decision making agenda, which involves outlining decisions and agreements that need to be made in the process of developing and implementing policy. This is reflected in the work packages of the first NSABB working groups, which for example included groups tasked with identifying criteria for dual-use research. Finally, the NSABB also appeared to open policy windows (i.e. joining the problem, policy and political streams) by providing feasible responses to the dual-use issue, developed by experts from the relevant policy communities to the US executive, which could choose to provide support for the implementation of these policies.

The role played by the NSABB is also complicated because it potentially engages in the type of activities you would expect to see in risk pre-assessment (discussed in chapter two). This includes setting the scope of problem definition, the delineation and analysis of a wide range of policies in biosafety, public health and ant-terror domains as well as the selection of normative and scientific criteria for the identification and management of risks. Such a situation often places the NSABB in a precarious political position, making the institution prone to controversy. This point was highlighted most recently in the political fall-out surrounding the governance of two 'dual-use' pieces of research on Avian Influenza. With one detracting member of the NSABB arguing that the institution had found itself in '*uncharted scientific and public policy waters'* in a 'leaked' letter to other NSABB members.[71]

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70 Interview senior National Academies of Science policy maker on file with the Author.

71 The letter was written by Michael Osterholm (Director of Institute of Center for Infectious Disease Research and Policy) to Amy Patterson, to an official at the National Institute of Health. . Letter Available online at http://news.sciencemag.org/scienceinsider/NSABB%20letter%20final%2041212_3.pdf.

### 5.4 Dual-Use Technology and the Politics of Security 2006-2012

As it currently stands, the majority of the gene synthesis industry[72], which is based mainly in Europe and US is signed up to one of two competing industry standards, each include technical protocols for screening orders. In essence these industry standards are a promise to the public and other stakeholders that steps are been taken to prevent terrorists from receiving dangerous sequences from these suppliers. Recently, the US government also produced a voluntary 'harmonized' standard. There are some subtle differences between the three standards - this includes most notably divergence in the recommendations on the level of reliance on human expertise. As it currently stands there also remains uncertainty about how companies will modify their practices to incorporate the most recent government standards.[73]

These vague policy outcomes, a result of several intertwined political process, are supplemented with other outcomes which involve untested working relationships between industry, scientists and security communities in a governance system, as well as concerns about the responsiveness of this system to the changing technological and security environment. For scholars such as Maurer, the current situation represents a moment of stagnation after a period in which more could have been done. In contrast, other commentators have also expressed optimism about the products of the previous decade as a good first step.[74] Naturally, such perspectives are based on a range of assumptions about the threats posed by polynucleotide synthesis technology, the way in which this issue should be dealt with and the realities of generating security policies in this area.

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72 Estimated to be around 80 % of global capacity as of 2009 (S. Maurer 2011, 1389)

73 However, to the author's knowledge there have been no substantive and systematic independent public investigations into the current implementation of these standards within industry since the publication of the guidelines.

74 An interview with George Church reported in *Nature* (Ledford 2010)

In the following section there is an examination of the political processes of the which have underpinned the emergence of dual-use policy. Following Maurer, distinctions are made between three channels of dual-use governance related to synthetic biology; the academic, industry and federal tracks. This distinction makes sense, in that each of these tracks operated according to distinct time frames and distinct logics, and in relation to different problem definitions. However, it is worth noting explicitly that these channels were not operating in isolation to each other.[75] As Maurer has already pointed out, individuals and organisations contributed to multiple tracks of policy development (Maurer 2011, 1426). The political significance of having multiple streams of policy development is a national context is also in itself an interesting line of enquiry which is developed within the following in-depth analysis.

### 5.4.1 The NSABB and the Synthetic Genomics Working Group 2005-2007

In late 2005, a synthetic Genomics working group for the NSABB was established to

> '*Examine the potential biosecurity concerns raised by the laboratory synthesis of Select-agents, and the broader field of synthetic biology; and recommend possible strategies to address these concern'* (Relman 2006)'.

The working group broke this task down into a two phase project (Relman 2006). In phase 1, they were to address the issue of de novo synthesis of select-agents, they would then go on to address broader biosecurity concerns associated with the field of synthetic biology in phase 2. This appears to be in-keeping with sentiments of the Sloan funded Maurer et al. report,(2006) which identified synthetic genomics as an issue of more immediate concern than other

[75] This has at times been complicated by two trends within the grey material produced within this area. First, in some documents produced by the NSABB there has been a tendency not to ascribe comments to specific individuals and representatives in meeting reports. This means that ideas can simultaneously appear in two channels, and it is unclear where they were initially introduced, and by whom. Second, authors of policy proposal documents have often by ignorance of design been quite selective about which parallel initiatives in other tracks that they acknowledge. This can also complicate the reconstruction of events. For example, the first major industry initiative did not acknowledge relevant NSABB activities in publicly available materials, despite the involvement of several of the authors with the NSABB process . The issue of so called 'Chatham house rules' in research on biosecurity policy is addressed in (Rappert 2009)

technologies which could be eventually produced by the field. The work of this NSABB working group, as well as its implications in US dual-use politics, is now examined.

Historically, the US had ensured against the misuse of select-agents via a containment strategy. It was understood that this system ensured that only responsible individuals had access to dangerous pathogens utilized in scientific research. Domestically, the system depended on select-agent agent biosecurity, in which only individuals granted permission by the NIH could possess dangerous pathogens. The system also depended on select-agent biosafety, which was implemented through NIH standards (the primary funder of US select-agent research); to which researchers had to comply if they were to receive support. The emerging field of synthetic genomics was understood to challenge this existing strategy in fundamental ways in the report produced by this working group (NSABB 2006). First, the field of synthetic genomics was associated with the movement of increasing complex polynucleotide synthesis out of NIH funded labs and into the hands of an emerging industry. This industry was not necessarily covered by biosafety guidlines, which covered the safety practices and containment measures when dealing with select-agent pathogens. Added to this more general concerns in relation to recent changes of the select-agents programme were also raised in the synthetic genomics forum, leading the NSABB recommendations which were relevant to a much broader swathe of the life sciences than the field, and in particular biodefense activities. These recommendations focused on the existing legal characterisation of what constituted a select-agent, which appeared increasingly outdated as human understanding and ability to manipulate the agents had increased.[76]

The Synthetic Genomics Working Group made two key recommendations to government which were relevant to the oversight of technology associated with the field of synthetic

[76] A Broad overview of resultant actions is available on the Select Agent Programme website: http://www.selectagents.gov/resources/synthetic%20genomics.pdf

biology. The first recommendation directed relevant agencies to engage with the scientific community and industry to raise awareness and give clarification in relation to existing legal requirements upon individuals working with and synthesising select-agent organisms[77]. The second recommendation directed the US government to charge the relevant agencies with the development of harmonised industry standards for handling polynucleotide synthesis orders.[78] The group had also considered several other options for the oversight of synthetic genomics, which included:

- *restricting access to new sequence information about Select-agents;*
  *Monitoring the sale of chemicals and lab equipment used to synthesize DNA;*
- *voluntary/involuntary surveillance/tracking of researchers/students using or trained to use synthetic genomics;*
- *modifying the SAR so that all select-agent genomes are covered; and*
- *Modifying the SAR or issuing new regulations defining Select-agents in terms of their sequence.*(NSABB 2010a, 8–9)

The working group stated that they:

> '*Chose not to adopt such recommendations because they are either not feasible, likely to be ineffective, and/or would unduly hinder scientific research. In certain instances, science has not advanced to the point that such recommendations could be implemented'*(NSABB 2010a, 9).

This decision however was not only informed by decisions on technical feasibility. It was increasingly apparent at this time that federal regulations were not likely to be forthcoming in

[77] Recommendation 1: The NSABB recommends that HHS and USDA collaboratively develop and disseminate harmonized guidance to investigators and nucleic acid/gene/genome providers concerning the SAR with respect to synthetically-derived DNA. Specifically, the Departments should provide clarification of what genetic elements or genomes are covered by 42 CFR 73.3c and 73.4c. Such clarification should include a list of the organisms whose genomes are explicitly covered and where the reference sequence can be found, and instructions for whom to contact if an investigator or provider has questions about covered genetic material. There is also a need for HHS and USDA to increase awareness among investigators and nucleic acid/gene/genome providers about their responsibilities to know what they possess, manufacture and/or transfer in order to comply with the SAR.

[78] Recommendation 2: The NSABB recommends that the USG should charge relevant federal agencies, in consultation with outside experts to 1) develop a process to be used by providers of synthetic DNA for determining the sequences for which to screen (Select Agents or otherwise); 2) develop and promote standards and preferred practices for screening orders and interpreting the results, and require that orders be screened by providers; 3) draft Points to Consider for determining whether genomic material that does not exactly match the genomes referenced in Recommendation 1 should be considered covered under the SAR; and 4) develop standards and practices to be used by providers for retaining records of orders for gene-length or genome-length nucleic acids, and require that orders be screened by providers. The NSABB also recommends that the USG require federal grantees and contractors to order from providers that screen and retain information about requests for Select Agent sequences following standards and practices developed by relevant federal agencies, and foster an international dialogue and collaboration with the goal of developing and implementing universal standards and preferred practices for screening sequences and related matters.

relation to this issue area. This suggests that while regulatory approaches were 'considered', it is unlikely that those involved took the prospect of drastically altering select-agent regulations, or else developing stringent regulatory material and researcher controls that seriously.

The political context of the NSABB recommendations, in particular the extent to which government were willing to let industry and academia take a lead on this issue, are revealed in the minutes of a NSABB synthetic genomics working group meeting at the time. During this meeting , a representative from the US Executive Office who had been '*playing a very important role …in helping shepherd [the NSABB] report into the system'* (David Relman NSABB 2007, 4) gave a presentation on how the report had been understood and responded to. First, he highlighted that the NSABB's call for the US government to develop polynucleotide synthesis screening practices (comments of Ben Pietro, NSABB 2007, 22–23), could be interpreted ( and indeed had been) as a call for the development of regulatory framework.[79] He noted, however, that there were alternative approaches to regulation and that regulation was not in line with thinking in the Executive Office. Furthermore, he outlined the extent to which the Executive Office was taking the lead from the Sloan Report process, stating that the inter-agency process to develop screening standards would draw on:

> '*policy option reports pertaining to screening that have been developed by folks out at UC Berkley, the Sloan Foundation funded study at MIT, JVI, CSUS, and also some other publicly forwarded options for consideration.'*(Comments from Ben Pietro NSABB 2007, 23)

It was in this context that governance initiatives would emerge in relation to polynucleotide synthesis technologies within the US. A context in which the US government were unwilling to take the lead, or develop regulation directed at the issue.

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[79] The recommendations themselves are ambiguous in relation to this point. Calling for the USG to work with others to develop screening practice standards- but not outlining how such a system should be enforced, or whether government departments should be legally mandated to develop and implement such standards.

### 4.4.2 Industry Stream Emergence and Initiatives 2006-2010

By late 2006 a consensus had emerged in which industry was envisaged as central gatekeepers in a system designed to keep dangerous gene sequences out of the hands of terrorists.[80] This had been reflected in discussion in both the academic and federal streams. The details of the role of industry in this system were yet to be worked out at a federal level; however it was clear at this early stage that it would take time for the USG to produce the guidance requested by the 2006 synthetic genomics report. Meanwhile, industry was beginning to organise into associations. The first of these was the International Consortium for Polynucleotide Synthesis (ICPS), an industry association which included Geneart, Codon Devices, Blue Heron, and Codagenomics Codon devises. Within this organisation there were three key individuals with an interest in biosecurity issues associated with synthetic genomics. Leading scientists George Church and Drew Endy had already been prominent in biosecurity discussions. The third individual was John Mulligan who was President and CEO of Blue Heron Biotechnology, an individual who had already been active in the federal policy stream. Blue Heron were also acting as a test bed for a software development and data analysis interested in developing sequence screening software (CRAIC computing).

The ICPS published a policy proposal in 2007 in *Nature* (Bügl et al. 2007) . The purpose of this document was to cement the role of the ICPS in the development and implementation of biosecurity governance. This was reflected in the way the policy proposal was presented, as well as the content of the policy proposal. In the 2007 publication, it is apparent that those involved wished to present themselves as taking the lead in the development of policy in relation to the dual-use issue. In the document there is no mention of activities in the federal stream, specifically the synthetic genomics working group, which was advocating a similar

[80] This was also reflected in FBI outreach projects to Industry and the acamdemic community at this time.

approach to the one outlined in the document.[81] In relation to the policy proposals themselves, it is worth noting that the only other policy option discussed is that of George Church which is categorized as '*impractical*' without further justification.

Reflection upon this early ICPS initiative is revealing in relation to the principles that would continue to shape industries engagement with the issue. The first question relates to the motivations of industry to engage with the governance of dual-use technology. One argument is that even engaged aspects of industry were still quite ignorant to existing responsibilities under existing US law, and this was worried them. Those following the work of the NSABB working group would have been aware that aspects of the gene synthesis Industry may have unwittingly been contravening select-agent law by sending unknown biological substances by post, and second in the context of inadequate screening practices, may have also been unwittingly producing, handling and transporting materials covered under select-agent regulations without legal authorisation.[82] This was perhaps enough in itself for leading aspects of industry to wish to get their houses in order. The second motivation was the need to represent industries' interests in the development of the emerging governance system directed at polynucleotide synthesis which was under discussion at a federal level. A final incentive was that there were perhaps competitive advantage and financial reward to be gained by industry who engaged with the biosecurity issue early (Maurer 2011, 1431). This perspective was based on a reassurance from prominent aspects of the synthetic biology community that researchers would only deal with industries that screen, as well as the prospect that the USG (more specifically it's scientific funding bodies) would ensure that that

81 Those involved in the drafting of this document had been actively involved in WG process.

82 This is because DNA Synthesisers may have been producing sequences were in themselves infectious. ….Such genomes include RNA viruses that are in message sense, DNA viruses that do not require a special viral enzyme to replicate and nucleic acids that, if inserted in the appropriate host system, can create a fully functional toxin (Attachment 2). Accordingly, synthesized genomes and toxin expression systems of these Select Agents are also regulated.'
http://oba.od.nih.gov/biosecurity/pdf/Final_NSABB_Report_on_Synthetic_Genomics.pdf pp5.

all publicly funded researchers follow suit in this regard.[83] A further incentive was the prospect that leading aspects of the industry could secure biosecurity funding from government to development proprietary practices, which would also provide a source of revenue and a competitive edge. The second set of observations relate to how industry pursued interest in relation to the dual-use issue. There were two facets to industry engagement with this issue area.

The first was through the federal track; industry certainly helped refine the scope of the problem definition and the closely related process of policy selection by providing technical expertise on the feasibility of policy responses. However, a second facet of this approach was more of that or a primary securitizing actor- this is in the sense that industry established its own channel of policy development. Both sets of activities provided the context of the next major round of political activity directed at the polynucleotide synthesis sector.

Despite these early successes however, when funds failed to materialise for the ICPS it appeared increasing likely that little would happen in a US context in relation the development and implementation of industry standards until the USG produced its guidance. However it would be developments outside of the US which would serve to motivate further development in policy discussion in late 2009. These developments would also have more fundamental impacts on the politics of the industry stream of policy development. In the following section there is an examination of the process by which the emergence of the ISAB, a European gene synthesis consortium, would impact on the US industry policy stream, as well as the consequences of this.

[83] The NSABB report of 2006 (NSABB 2010a) recommended that the government should require federal grantees and contractors to order from providers that screen and retain information about requests for Select Agent sequences following standards and practices developed by relevant federal agencies (See 2.1.1 – 2.1.4).

### 5.4.2 The impact of the European Industry Association on the US Industry Stream

In April 2008, representatives of the founding members of the ICPS were invited to a workshop run by the Industry Association of Synthetic Biology (IASB).[84] The IASB had been established in 2007 by a handful of European synthesis companies,[85] many of these individuals involved had also contributed to the Sloan funded report (Rabinow and Bennett 2012, 144). The founding members of the institute had been considering the establishment of some form of industry association since early 2006, to help ensure the continued development of the field. Some of these members also had a particular interest in biosecurity issues, in the context of concerns in both the US and the EU.[86] This concern extended not only to the requirement for responsibility within the industry, but also the requirement to ensure against public backlashes against the industry.[87] The meeting resulted in the establishment of a work-package of activities to be undertaken by the members. The IASB approach jarred with the thinking of some pioneering US companies in two senses. The first related to the way in which the IASB went about developing policy and engaged with other stakeholders. The second related to the nature of policy proposals. Added to these disagreements, growing support within key circles within the US for the ISAB approach threatened to undermine the control the pioneer US industry had to set the terms of industry stream governance. This resulted in a period characterised as a 'standards war', which is now examined.

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84 This would be one of the last publicly known activities of the ICPS, which quietly folded soon after IASB workshop

85 ATG:Biosynthetics GmbH, Biomax Informatics AG, Entelechon GmbH, febit synbio GmbH, MWG Biotech AG and Sloning BioTechnology GmbH (Bernauer et al.. 2008)

86 In 2006, the Guardian conducted a similar piece of investigative journalism to the New Scientist which had brought to public attention the nature of industry screening practices my placing an order for part of the small pox genome, it found that 'one did not screen customers or sequences, one carried out checks on customers only and a third checked customers and had carried out a pilot study on screening DNA orders but is not currently doing so'. (Randerson 2006)

87 Interview with industry representative. On file with Author.

In the context of the failed ICPS initiative there was an awareness within engaged aspects of the synthesis industry that there was still the need for development of screening practices in both the US and Europe.[88] However, it appeared at least for a short time post-2007 as if these companies would no longer pursue their interest in the industry stream of policy development and instead focus on impacting upon the slower moving federal stream when it was felt necessary. However, following this false start, events in Europe would serve to motivate a restart of the US industry stream of policy development. The announcement of the ISAB work package had been well received by *Nature* in an editorial in September 2008, which made no reference to the work of the US based ICPS initiative (Nature 2008). Added to this the decision[89] of the ISAB to attend the BTWC,[90] had also contributed to the initiative being tracked by interested aspects of the US security community. Such a situation must have been troubling for engaged aspects of the industry that now faced the prospect of another organisation filling the vacuum in the US industry stream left by the petering out of the ICPS initiative. Importantly, the organisational structure and *modus operandi* was also different to that of the ICPS, being more inclusive of broader stakeholder input than the corporatist approach of the ICPS. Added to this, the ISAB's support for the use of a human expert as part of the screening process was also disconcerting for some aspects of industry which felt that a human step in the screening process would unnecessarily slow orders and add extra expense. These factors were enough to motivate Gene-art[91] in collaboration with the US firm DNA. 2.0 to react with a counterproposal (Check Hayden 2009). This proposal was not well received, and was dead within a matter of weeks.

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88 Especially Blue Heron, and Integrated DNA Technologies who had been involved with the ICPS proposal.

89 An action encouraged by Professor Kathyrn Nixdorff at an IASB meeting (Bernauer et al.. 2008, 18)

90 At the 2008 MSP Germany submitted the ISAB code of conduct as a working paper BWC/MSP/2008/WP.3. The ISAB also gave a presentation. Available at :http://www.unog.ch/80256EDD006B8954/%28httpAssets%29/55E15F1EB02210EDC125751A004B1A7E/$file/BWC_MSP_2008-Presentation-IASB.pdf

91 Gene-art, a German company, destined to be bought out by the international biotech firm 'Life technologies' which had been involved in the first ICPS biosecurity initiative

The reasons for the failure of the Gene-art/ DNA 2.0 proposal are revealing about the role of industry as a secondary securitising actor, and the constraining forces which acted upon it within the industry stream of policy making. Since 2006, it had been apparent that the main role of industry in dual-use governance would be to implement some sort of screening. It was also apparent that industry could be expected to exert some influence in the development of this policy. However, between the 2007 ICPS proposals and the summer of 2009, there had been some fundamental changes in the politics of the US industry stream which were underpinned by work at the IASB and the appeal that the approach had to US policy-shapers. Essentially, the work of the IASB had become a type of gold-standard against which any proposals could now be evaluated. This gold standard included both technical criteria, such as the use of a human screening stage, as well as political criteria such as inclusivity and openness, which has been absent in the first US ICPS proposals. This then suggests a potential for a very real impact of European industry security practices and politics upon the politics of US biosecurity.

As a consequence, in order for Gene-art/ DNA 2.0 to impact in this, they were forced to develop a second proposal, in collaboration with several other of the largest gene-synthesis providers, a collaboration undoubtedly galvanised by the pace of developments in Europe. This proposal closely resembled that of the ISAB with regard to the technical requirements it placed upon industry.

So to sum up, prominent aspects of industry, in collaboration with leading aspects of the synthetic biology managed to establish a novel channel of policy development and implementation in the context of community action at S.B 2. In many ways this channel initially held the promise of escaping some of the political and procedural realities that frustrated the development of policy in both the academic and federal streams. This act was

'primary' in nature as it opened up a political channel of policy development that bypassed the understood political realities at the time in the name of security. However the act was also secondary as once the fissure had been conceived, the ICPS proposed specific policies to be implemented through this channel. Ultimately the ICPS would succeed as a primary securitizing actor as it established the industry channel of policy development, making such processes appear a feasible political reality. In the second sense however, as a secondary securitization actor the ICPS proposal failed to reach the implementation stage.

Once established however, the industry channel did not exist in a static political domain and US perspectives on activities of the ISAB in Europe modified the expectations upon industry as an implementer of security policy within the US. It would be the drafting of the federal guidelines on screening which would be the next major event that impacted upon the politics within this channel.

### 5.4.3 US Inter-Agency Process and Federal Guidance on Screening Practices 2007-2010

In this final section, the process, politics and outcomes of the US federal track of dual-use technology governance activities in the period 2006-2011 are examined. This period essentially involves studying the way in which recommendations from the 2006 NSABB report were translated into policy outcomes. The major part of this response came in the form of an NSC inter-agency process which led ultimately, after public consultation, to the publication of '*Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA'* (Department of Health and Human Services 2010).[92] These guidelines are analytically

[92] The second part of the response involved a National academies report entitled 'Sequence-Based Classification of Select Agents: A Brighter Line'. The purpose of this report was to examine the scientific and technical developments required to develop a means to improve existing select-agent characterisation systems ( which rely largely on physiological characterises) which were being

interesting as they represent the culmination of US government activities directed at the immediate dual-use technology problem associated with the emerging gene-synthesis. This provides a moment upon which to reflect upon the role of the US government played in the overall process of policy development in relation to the issue.

An interesting observation in that academic and press coverage on the emergence of federal guidelines has been divisive. Some placed a positive emphasis on collaboration between government and industry in the development of standards. However, others worried that the government had been cowed into action that was too lax (Bhattacharjee 2009). The arms control community in particular favoured the latter view suggesting that the government had adopted a moderate approach to defining and responding to the risk. For example, it was suggested that the guidelines only covered double-stranded DNA (neglecting the threat posed by single stranded DNA viruses or the construction of viruses from multiple ssDNA orders (i.e. oligos)). It was also highlighted that the guidance was voluntary rather than legally binding, based on the assumption that NIH enforcement would be enough to ensure compliance. It was also claimed that the government's screening protocol was weaker than the ones currently favoured by industry (See for example: Maurer 2011; Ledford 2010; Eisenstein 2010).

Within the US context, since at least the NSABB report on synthetic genomics, there had been an expectation that more far ranging and enforceable controls will be developed at federal level in relation to gene-synthesis technology within some circles. However, the primary response at federal level has been voluntary guidelines which are narrow in scope. This raises some interesting questions. The first set relate to why it was assumed the

undermined by the ability of scientists to genetically modify and hybridise bacterium and select-agents, blurring the line between what constituted a select-agent and what did not.

government would favour strong forward-looking regulation. The second relates to why the government have not adopted such an approach.

In relation to the first point, the characterisation of the government as 'pro-regulation' stemmed from two primary areas. First, within the public health domain, the bio-defence community in particular had repeatedly pointed out the dangers of federal over-regulation of the biosciences (For example Franz et al. 2009). This created an environment in which discussion of dual-use research regulation had become polarised. Within the NEST domain the ETC's involvement with the academic stream of policy development also led to the characterisation of the political situation as involving a dichotomy between technological innovators who were opposed to government regulation, and the state, which if pressed, would bring regulation to bear on safety and security issues. Added to this the announcement that the US government would develop guidelines through the National Security Council Interagency Process further cemented outside perspectives that the US government was looking to implement strong policy informed by national security over the longer term - naturally such perspectives were informed by the draconian national security responses of the post-9/11 era. In the context of the pro-regulation characterisation of the national security community at the time, it appeared likely that this process would become a gateway into stricter regulation of industry in the name of national security.

It is clear, however, that such perspectives do not reflect the current US approach to the regulation of cutting-edge dual-use technology and the fact that federal engagement with the interagency process has not become the basis for further federal initiatives to regulate the field, is testament to this. This then leads to questions about the actual nature of the federal track of policy development.

Upon further investigation into the interagency process, it becomes apparent why the federal track has favoured moderation, rather than more draconian measures. First, it was public health rather than homeland security institutions which took the lead on this issue. The interagency process was established by the White House Office of Science and Technology Policy and the National Security Council; however it would be the HHS[93] which would be tasked with taking the lead on this issue. The reasons for this decision were not made explicitly in public, but the decision reflected the prevailing wisdom at the time which prioritised the role of the HHS for three reasons. First, the HHS, through the work of the NSABB, had been key to the emergence of the issue of gene-synthesis oversight on federal agendas. Second, the HHS already had substantial governance competencies and expertise in biosafety and select-agent oversight through its sub-departments. These two areas of governance were understood to be of central importance to the oversight of dual-use technology following activities in both the academic, federal and industry tracks. Added to this, the HHS had already been identified as a key institution in ensuring compliance within industry and the scientific community. The department were and continue to be the main funder of scientific research in the fields of public health and bio-defence within the US.

With the HHS in charge, the development within the federal track would continue to reflect the consensus and technical episteme that had emerged within leading aspects of the academic and industrial community, which had repeatedly asserted itself against a regulatory approach, and so limited the definition of the dual-use issue to those risks which could be addressed by screening focused approaches. The public health community were, after all, keen to ensure that vital public health and biodefense research could take place in a way that was not unduly fettered by novel regulation; there was also a faith within leading aspects of

[93] Specifically, the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health and Human Services (HHS)

the public health and biodefense community that community based approaches (as seen in biosafety) preferable to the implementation of new, untested and possibly cumbersome regulations.

### 5.4.4 Conclusion: Gene Synthesis Technologies and the Politics of Security

The analysis above has highlighted in some detail the answers to the questions of who securitises how, and with what effects in the US context. Before moving on to the discussion of the securitisation of dual-use research it is worth making a few remarks to sum up this process.

In relation to the question of *who* generates security policy with relation to the issue, the answer appears to be that *consensus* between the scientific community, industry and the government has meant the securitization should be understood as a collective activity between these actors. The construction of consensus however relied on a dynamic in which the threat of government enabled coalitions to form between industry and academia which lead to the development of a model of oversight, embedded in assumptions about science and technology drawn from an episteme developed during the major ELSI initiatives within the field. Later on, developments in Europe would also motivate industry to re-assert its role as the predominant secondary securitizer within the field. This role would be cemented by activities in the federal stream which resulted in the release federal guidance. This left future policy develop in this area reliant on the actions of industry in the foreseeable future.

In relation to the question of 'how' actors securitized, there were attempts at both primary as well as secondary securitization. The initial attempt by Maurer to create a channel of primary securitization failed on its own terms, however it would serve to facilitate securitization in other channels that emerged. The activities of the ICPS represent an example of successful

primary securitization, as it resulted in an industrial channel of policy development emerging, however these early actions failed as an act of secondary securitization.

In relation to the question of *what* was securitized it is apparent the emergence as well as scope of dual-use technology, securitization was dependent on a focus on industry as a central gate-keep in biosecurity. This focus meant that later discussions focused the development of scientific conventions for risk assessment as well as screening practices once this framing became dominant. The dominance of this model led to the externalisation of broader and more forward-looking concerns from politics in relation to this issue.

### 5.5 Dual-Use Research and the Politics of Security

The academic field of synthetic biology has received a disproportionate level of attention as a source of dual-use concern within the US, compared to other contemporary emerging techno-scientific fields. This raises the question: why do concerns about the dual-use nature of gene-synthesis technologies and more general concerns about biomedical research come to focus on the broader field of synthetic biology? For example, the field of nanobiotechnology is contemporary to synthetic biology and is very similar in organisation as well the technological and epistemic aims of researchers involved. Added to this, some branches of the field are also dependent on foundational gene-synthesis technologies in a comparable way to some sub-fields of synthetic biology.

The reasons for this discrepancy stem from institutional links between emerging gene-synthesis technologies and the emerging academic field of synthetic biology in the early to mid-2000s. In the early 2000s George Church, Craig Venter and Drew Endy (who would become fundamental to the emergence of the field of synthetic biology) had already been involved in high-level dual-use discussions about viral synthesis technologies and techniques.

This in itself could have been enough to provide a 'bleed' of dual-use concerns from polynucleotide synthesis technologies to the broader field of synthetic biology. However, this in of itself did not provide a forum for such discussions to take hold. Instead, it was initiatives within the NEST domain[94] which would prove fundamental to cementing broader dual-use concerns on the US ELSI agendas as early as 2004. This, it must also be noted, represented the first ever major engagement of ELSI researchers with dual-use issues. The announcement that NSABB Synthetic Genomics Working Group would also be turning its attention to broader aspects of the field of synthetic biology once it completed its work on polynucleotide synthesis technologies also undoubtedly provided an extra incentive to keep the issue on the ELSI agenda in the US context in this early period.

This institutionalisation contributed to initiatives which discussed the broader dual-use potentials of synthetic biology. These discussions would go far beyond immediate concerns about the misuse of polynucleotide synthesis technologies by terrorists. They would also inspire academic analysis which was more anticipatory, and reflect on a broader range of misuse scenarios - including importantly the misuse of the field by states. However, as now should be clear, secondary securitization does not equate simply to the rhetorical labelling of an aspect of a field as being as a security concern by certain actors. It also involves the development of policy directed at that aspect, which makes that aspect subject to a risk governance regime.

Rabinow and Bennet argue that there have been no standards developed to allow for the dual-use issue to be converted into a mangle risk which is the assumed aim of the institutions and actors they study (2012, 158). To this end, they argue that current dual-use policies, particularly those of scientific self-governance are actually pre-emptive of further

[94] Primary in the form of meetings and commissioned research which led to a series of reports and other documents Including: (Garfinkel et al. 2007; S. M. Maurer, Lucas, and Terrell 2006)

intervention that may redress the broader issue of the requirement for regulator to engage 'upstream' with the innovation process. To place this idea in terms of arguments developed in chapters two and three, this essentially equates to the claim that in the absence of the political and institutional tools to redress broader dual-use issues, the only issues currently being turned into risks requiring a response are those that are already been addressed under existing governance frameworks, or can be addressed in the immediate future through the incremental (and modest) changes to these systems. This cordons off a large range of dual-use concerns that cannot be dealt with through existing knowledge, material and technology containment systems.

For two reasons however, it is likely that ELSI assessment activities will have been of some political consequence in the study of the securitization of dual-use research. First, such activities have encouraged the engagement of other actors through raising the profile of the field and bringing different assessment rationales to bear which may challenge the dominant discourse. Second, there have been political developments outside of the field of synthetic biology that ELSI activities (and associated capacities) seem to have fed into[95]. In the following section questions about the role of such engagement is of central importance in the study of the political process that has given rise to the securitization of specific dual-use aspects of synthetic biology research.

### 5.5.1 The NSABB and the Governance of Dual-use Synthetic Biology Research

In 2007, the NSABB published a report on the '*Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information'* The report essentially called for existing Institutional Biosafety Committees, in

[95] Referring back a point made at the beginning of the chapter, when looking out from synthetic biology community as an analysis, there is likely a tendency to underplay the political reconfigurations that occur outside a field as it develops

state funded institutions, to address dual-use concerns as part of the normal internal review process which ensured that the institution was in-keeping with relevant guidelines related to biosafety. These recommendations were deemed inadequate within some non-proliferation and civil society circles. These concerns were, in part, based on a general mistrust of the transparency and legitimacy of biosafety oversight, but also concerns that this approach would act to placate broader concerns about state-level bio-defence research on dangerous pathogens, or focused too narrowly on single experiments rather than trends in biotechnology innovation (see for example Sunshine Project 2006) . In the context of the emerging field of synthetic biology however such critiques would matter little. As the NSABB model would have substantial impact on the evaluation of scope of misuse risks in the coming years.

### 5.5.2 The Sloan Report

The Synthetic Genomics: Options for Governance report (often referred to as the Sloan Report) (Garfinkel et al. 2007), represents the most substantial publicly available investigation into the broader dual-use implications of the emerging field of synthetic biology. The ninety-six page document emerged out of a twenty month process, and involved a central panel of twelve experts, six commissioned academic papers and three invitation-only meetings. The Sloan Report adopted a framing of identifying dual-use risks associated with synthetic biology research which closely followed that of the 2006 NSABB report. Specifically in relation to the issue of research oversight, the starting assumption of the Sloan Report is that the principle investigator of a scientific project is best placed to identify and address risks associated with his work in the context of appropriate institutional support and oversight (specifically institutional biosafety bodies). On the basis of this assumption, the Synthetic Genomics report externalised broader aspects of the dual-use issue which could not be identified and dealt with at this intervention point. Specifically, this excluded the issue of

the contribution of the field to state-level weapon development or, more long term contributions of single experiments to misuse scenarios which were not likely to be foreseeable during the IBC process.

As the Sloan research group had utilised the same starting assumptions about the nature of the dual-use issue proffered by the NSABB, when examining the field for dual-use potential, it is then unsurprising that this investigation did not reveal any scientific development that generated challenges significant enough to bring into question the NSABB's proposed model. Added to this, as the Synthetic Genomics Working Group would draw heavily on the expertise and framing of dual-use synthetic biology developed during the Sloan report process, this inevitably lead to a bias which precluded the NSABB group from identifying broader dual-use concerns which could not feasibly be dealt with under its proposed oversight framework.

The experiences of the working group led to two substantial conclusions relevant to the continuing governance of the field of synthetic biology and the governance of emerging biotechnologies more generally, which were communicated in a 2010 report. First, the group found that the oversight framework the NSABB had proposed back in 2006 could adequately address the current biosecurity concerns raised by the field of synthetic biology. This also served to validate the framework in terms of its ability to handle the challenges presented by emerging scientific fields, to this end the NSABB also reasserted the requirement for the government to implement its recommended framework.

Indeed, since 2006 whenever developments in either politics[96] or science and technology appeared to challenge the suitability of the proposed NSABB model, the assigned working

[96] Such as the implication of a senior US biodefense researcher Bruce Irvins in the fallout of the 2012 Amerithrax attacks.

groups focussed on clarifying or amending and supplementing their favoured approach, rather than question it. The field of synthetic biology, as the first major test case for the NSABB, raised several issues which the NSABB understood should be addressed in order to sustain the viability of its proposed framework which focuses on the responsibility of the scientific community; specifically the issues of:

1) non-life scientists entering the field,

2) the emergence of the amateur community, the

3) international spread of the field as well as the

4)Rapid pace of the development of scientific and technical capabilities.

The way in which the NSABB working group chose to address these issues is now discussed. I argue that these recommendations have limited impacts on the scope of synthetic biology which is likely to be the subject of dual-use review at institutional level in the near term in the US context, despite the appearance of the NSABB to be engaging with broader more forward-looking concerns. It is worth reiterating is even in respect to a relatively narrow range of the broader dual-use problem that the NSABB has concerned itself with, which by and large relate to terrorist misuse scenarios.

### 5.5.3 The Impacts of the "Addressing Biosecurity Concerns Related to Synthetic Biology" Report

Over a period of several years, the Synthetic Genomics Working Group had been examining the nascent field of synthetic biology as a source of dual-use concern. In-keeping with the trend set by the Synthetic Genomics: Options for Governance Report the primary focus of the investigation was the approaches currently being championed at leading US institutions, specific top-down and bottom-up approaches to engineering biotechnologies (NSABB 2010b, 8). This scope was actually quite narrow, neglecting broader aspects of the field including

research lines directed at proto-cell creation, the development of unnatural components as well as research on synthetic microbial consortia, which were in part ignored due to the infancy of these approaches and the absence of immediately foreseeable misuse scenarios (NSABB 2010b, 16). A trend that had been set in the Sloan Report and would be repeated in the 2010 presidential report on bioethical issues.

The 2010 report highlighted several challenges raised by the field of synthetic biology. First, was the idea synthetic biology innovation was occurring outside of federally funded life science labs. This potentially challenged the existing approach to biosafety oversight which focused primarily on NIH guidelines for laboratories. Second, the convergent nature of the field meant that researchers from non-biological backgrounds, and importantly without NIH association or biosafety training, may potentially become PI's in synthetic biology research. Added to this the field appeared to be moving not only out of the labs into industry, but also into the hands of amateurs. This meant that the main institutional infrastructure that the NSABB model was dependent on was absent. The response of the NSABB was to call for outreach to these communities, and the requirement to make industry and the amateur community subject to some form of local-level institutional review. Substantial federal support will be needed to aid and ensure the implementation of this across these contexts- which will not only involve educational impacts but other forms of intervention to ensure these communities are given appropriate levels of support to discharge these responsibilities. Currently, while there are examples of more substantial initiatives, such as those developed by the FBI - these are largely proof of concept-type initiatives.

The second major issue, related to the ability of the oversight system to respond to; trends in the practice of scientific research, as well as, the augmenting qualities of emerging foundation technologies and scientific discoveries on researcher capabilities. A case in point,

was the ability of institutions to identify, monitor and respond to trends in synthetic biology which may cause a dual-use concern. The 2010 report on synthetic biology identified such trends; specifically the emerging amateur community as well as emerging foundational technologies. However, the recommendations of the working group had been greatly facilitated by evidence and working relationships developed during the the Sloan Report process. In this context, the call for a federal tech-watch initiatives within the 2010 report is not unsurprising and reflects an appreciation of the absence of federal attention and support to examine to more forward-looking issues.

### 5.5.4 Conclusions: Dual-Use Research 2006-2010

So far it has been argued that the NSABB and ELSI projects which have assessed the emerging fields have adopted a specific framing of dual-use issues. This has been as a result of the NSABB's pragmatic approach to defining the scope of the dual-use research problem. While the NSABB approach has yet to be implemented[97] in relation to state-funded research institutions dealing with non-classified research, the assumption remains that this model can be rolled out across industry and the emerging amateur community. As a result the NSABB approach can only respond to a limited range of dual-use concerns. This specifically involves scenarios in which single pieces of research raise 'obvious' dual-use concerns when dutifully assessed against the NSABB's recommended rubrics. This approach is designed to keep the results of dangerous research (both biological materials as well as information) out of the hands of terrorist groups. Even if the approach was to be implemented in the ways most optimally envisaged, the approach can still only a dress a narrow range of scenarios of

[97] It is of course possible to argue that the activities of the NSABB and the patchwork of education projects that emerged have insured that is already a de-facto system of screening within the field of synthetic biology- in keeping with arguments made by Maurer back in 2006, in relation the engaged and informed nature of the biosecurity community. However such arguments seem rather misleading as even if generous assumption are made about the levels of awareness of dual-use issues, this does not constitute the institutional capacity to identify and respond to issues.

terrorist misuse. This is because it involves a screening system which adopts a case by case approach with no formal requirements for institutions to report research of dual-use concern to higher institutions. This suggests that it is unlikely that challenges beyond the immediate foresight of local institutions will be identified and brought under the scope of dual-use governance. As has already been highlighted however, the adoption of the limited NSABB heuristic by the Sloan Report, suggests that it is unlikely that other institutions with the potential capacity to construct dual-use risks, will generate concerns beyond those which can be addressed by the existing system (for example the proposed tech-watch schemes). The work of the NSABB then represents the establishment of a pre-dominant episteme of dual-use governance within the US context - which appropriates biosafety modes of risk framing and management in the name of nation security. Undoubtedly then, the work of the NSABB has shifted the focus of dual-use politics firmly away from state-level regulatory intervention and instead diffused responsibility for the issue within the scientific community and increasing industry and the amateur community.

### 5.6 The Prospect of Reinvigorating Techno-Science Governance 2009-2012

So far, discussion has emphasised the way in which narrow- and pragmatic-guided problem framings have emerged within community and government level political process. In this final section there is a more cross-cutting analysis based upon recent developments which potentially suggest a revival in interest of broader range of concerns, as discussed in the early Maurer report in relation to the techno-science of Synthetic biology within the US. These developments do not only stem from the NEST domain, where the concept of a dual-use techno-science first entered the political discourse, but also the involvement new actors with the funding and governance of the field. In the following section two types of development are discussed. The first relates to the promise of a new form of politics in relation to

governance of dual-use synthetic biology and is a direct response to the 2010 President's Council on Bioethical Issues (PCBI) report on synthetic biology. The second relates to more incremental developments in dual-use governance in recent years which reflect the predominance of existing dual-use problem framings.

The PCBI report was optimistic about the role it could perform in changing the prevailing approach to US governance of the field of synthetic biology. The report states that:

> '*President Obama gave the Commission a rare and exceptional opportunity in the world of presidential bioethics commissions to be forward looking instead of reactive. We are ahead of the emerging science, and this unique opportunity underscores the need for the government to act now to ensure a regular, ongoing process of review as the science develops'* (Presidential Commission for the Study of Bioethical Issues 2010, 3).

To this end the report made several recommendations which were designed to ensure that the emerging field of synthetic biology was governed in order to be in keeping with 5 ethi-political principles: (1) Public beneficence, (2) responsible stewardship, (3) intellectual freedom and responsibility, (4) democratic deliberation, and (5) justice and fairness. In relation to dual-use issues the report found no need for new regulations or institutions, it did however, argue that there was a need for wholesale re-evaluation of existing federal approaches to risk assessment because of the '*difficulty of risk analysis in the face of uncertainty—particularly for low-probability, potentially high-impact events in an emerging field'*. The report also called for specific attention to be paid to developments in the practice of science which may impact upon the suitability of existing oversight systems. In particular, the movement of life science research out of state-funded laboratories and into the hands of industry and amateur scientists. Such recommendations suggest the possibility of broader framing of the dual-use issue emerging within the US discourse, in which the government plays a greater role in facilitating, developing and implementing more anticipatory approaches to governance. Indeed, this has been epitomised most clearly by the work of

scholars at the Woodrow Wilson Centre, who have produced an online 'score-card' to assess federal activities in relation to the 18 recommendations made by the PCBI.[98] The recommendations also repeatedly refer to the prospect of engineering biosafety and biosecurity into emerging technologies, as well as the prospect that synthetic biology can provide novel technologies to manage safety and security risks - an important driver in motivating interest, particularity within the scientific community, in dual-use issues within the US in previous decade. The report also alludes to the new synergies that have emerged between security and law enforcement communities with academic, industry and the amateur community. This has involved a handful of proof of concept initiatives, such as FBI involvement in IGEM, amateur community outreach as well as a biosecurity hotline. Added to this, developments at SynBERC could also be interpreted as move towards improved bio-risk identification and management. In 2010, Rabinow was asked to step down as head of the ELSI thrust of SynBERC, the reason given by the NSF was that the thrust had paid insufficient attention to 'biorisks' (Stavrianakis 2012, 163).

However, there is certainly cause for some pessimism in relation to the prospect of a new era of dual-use governance. First, there has been an absence of federal action in response to the recommendations made by the PCBI report. The Woodrow Wilson centre have reported minimal federal activities, with many of these activities pre-dating the PCBI report (Wadman 2012). Second, research conducted by Rabinow and others at SynBERC has drawn attention to the challenges of anticipatory governance within this institution. In particular it has drawn attention to the entrenched values within the scientific community and research institutions which prevent the transformation of innovation practices in order to identify and address misuse concerns (Rabinow and Bennett 2012; Stavrianakis 2012). For example they have reasserted the idea that concerns about misuse and broader societal effects are currently

[98] Website: http://www.synbioproject.org/news/project/6627/

externalised from the innovation process (Rabinow and Bennett 2012, 153). Stavrianakis has gone even further than this, warning that the growth of attention to the idea of bio-risk management in recent years is in fact tantamount to a retreat within the SynBERC institution towards public engagement and reassurance within its ELSI thrust (Stavrianakis 2012, 155). These observations raise some interesting questions about the relationship between such risk-assessment and the prospect of anticipatory dual-use governance - an idea discussed in the final chapters.

A second cause for pessimism has been the narrow range of misuse scenarios currently addressed within the US discourse. For example, the PCBI report only discusses the issue of bioterrorism, and did not reflect on broader aspects of the field than the NSABB did in its 2010 report. This narrow problemisation is also reflected in the way in which the BTWC is not referred to as an appropriate international forum for the US to pursue discussions about the misuse potential of the field of synthetic biology. This suggests the continued pre-dominance of the NSABB conceptualisation of the dual-use problem within US politics in the foreseeable future. As was argued in the previous section, the consequence of this will be a continued narrow experiment by experiment and technology by technology focus of dual-use risk assessment which is not designed to identify or respond to the broader trends in techno-science. This, for example, includes the proliferation of powerful technologies and the growth of the biodefense imperative. In the context of military investment into the field,[99] such investment will potentially lead to exclusionary technologies in which security controls are 'engineering in' as well research which pushes up against the norms against biological and chemical weapons. Such concerns are as pertinent as they were in 2006 and yet remain marginalised from US discussion.

[99] The most recent DARPA project 'bio-foundries' for example invested $15.5 million into university and industry projects aimed at developing new foundational technologies for the production of GM materials

These observations reveal that the PCBI report may provide a politically useful endorsement for actors who are seeking to encourage a more systematic implementation of systemic risk assessment rationale in relation to anticipatory biosafety and biosecurity concerns. However it has also revealed the challenges of such an endeavour within the existing US institutional landscape. It has also revealed the extent to which rhetoric of transformation in relation to innovation processes thorough 'risk-management' may actually be understood as a means of deferring and externalising many dual-use concerns.

### 5.7 Conclusions

In the study of securitization a key focus has been upon the questions of who securitizes, how, under what conditions and with what effects. Within this chapter each of these questions has been attended to and it is worth taking each of these questions in turn before further discussion in the comparative and conclusive chapters.

In relation to the question of who securitizes, it has become clear that several different actors have emerged in relation to distinct dual-use aspects of synthetic biology. Not only have these actors sought to develop and implement security policies (secondary securitization), but they have also sought to alter the political conditions under which policies are developed. It has become clear that a coalition of industry and academia have become central to setting the agenda and selecting policy options over the previous decade. The NSABB has impacted upon the episteme within these communities, particularly with regard to its definition of dual-use research, but has struggled to pass initiatives which are not supported by industry, academia, and *ipso facto*, the state. This observation points to the idea that the question of 'what' becomes securitized is closely intertwined with questions of political feasibility, rather than being dependent on intrinsic qualities of specific aspects of innovation - a point that will become clearer still during comparative analysis.

In relation to the question of 'how' actors have made issues subject to security governance, several trends are evident. The first is that actions have tended to be solution rather than problem led. That is to say, in the absence of state intervention, only narrow aspects of the dual-use issue which could be addressed with minimum disruption and at minimum cost have been considered feasible. Polynucleotide screening is a case in point, as this policy option presented a narrowly focused, neat and relatively inexpensive policy option. In contrast, in relation to the issue of dual-use research, broad and forward-looking concerns have been marginalized as addressing these concerns would require much more developed national capacities to identify, respond to and where necessary restrict issues of dual-use concern. This means that for now, US discussions remain focused on reactive case by case analysis of problem experiments. A second observation has been that the primary audience of securitization activities in a US context has been the government itself. This is in the sense that in order to implement preferred security policy options, the engaged aspects of the academic and policy community have had to provide government with a feasible policy options. An interesting question which remains, however, is the extent to which it would have been politically feasible for the US executive to develop or implement regulatory alternatives in 2006 without the pre-emptive actions of industry and academia. There was, after all, decreasing public attention to bioterror concerns as well as constant pressure on government from the public health domain not to stifle public health and defensive research. This observation points to the idea that policy development and implementation in a US context was, by necessity, much more collaborative than polarised. It is this collaborative environment which has constituted the conditions under which specific favoured policy options have risen to prominence.

This is not to argue however, that there have not been technical disagreements over the implementation of such policy options. In the case of polynucleotide synthesis, these

disagreements have manifested in the development of competing standards of screening. Such disagreements have not always been of immediate consequence for policy however. For example, the NSABB had repeatedly called for the implementation of a federal review process for dual-use research of concern. However, during the period analysed within this research, the government chose not to implement such recommendations. This observation points to the idea that the political landscape of securitization is not just dependent on consensus within key policy communities within the policy stream, but also developments within the political stream. In this case, it would be events outside of the field of synthetic biology specifically concerns over H5N1 gain of function research, which would provide the political moment for the implementation of federal review policy in 2012. This observation reminds us that the promises of transformations of the relationships between innovation and regulatory systems periodically espoused within the US NEST domain cannot be initiated by activities within the field of synthetic biology alone.

In relation to the question of 'effects', a key idea is that it is possible to distinguish between consequences of securitization for the field of synthetic biology , as well as for future discussions of dual-use research and technology more generally. For example, it is clear that in relation to oligonucleotide synthetises, industry emerged as the pre-eminent actor in the development and implementation of security policy. It seems likely, such actions not only reflect the political environment in which they occurred, but may also in themselves set a precedent for industry engagement with dual-use governance in the future.

In the final two chapters each of these ideas is addressed as more cross-cutting themes are developed and analysed.

# Chapter Six: The Politics and Practice of Dual-Use Governance in the UK

### 6.1 Introduction

In the UK context, the politics of dual-use governance has been of a sporadic and nebulous nature. This, in the sense that there is no central political process, institution or discourse, which explicitly ties together activities in the various domains of dual-use governance. As a result, the dual-use issue constitutes a vague and uneasy political issue. Within the scientific community for example, when the issue is attended to, it tends to be understood as an add-on to ethics review activities, or as part of scientists' ELSI engagement responsibilities. This means that many scientists within the synthetic biology community see the dual-use issue purely in terms of public engagement, whereas others understand the issue to potentially require the development of extra risk management responses.[100] That being said, in practical terms there exists a real absence of clarity among key stakeholders about the role they can or are expected to play in response to a poorly defined issue. As one UK Synthetic biology PI stated during an interview when pressed on how to identify and manage the risks presented by the field: '*How do you find it? I find it very very hard to couch these questions*'.[101] Likewise in a recent House of Lords meeting, ten years after the emergence of dual-use life science issues emerging on agendas it was stated that:

> '*Given the boundaries between pure and applied research, defensive and offensive, civilian and military uses are unavoidably blurred. It is also important to better integrate biosecurity considerations into current public policy on biotechnology, nanotechnology and synthetic biology. I suspect that this is largely missing from current policy initiatives in these areas, not least within the European Union framework'* (Falkner 2013).

These initial themes serve to introduce an examination of political processes which have generated dual-use governance in the UK. This is in order to address the question of the extent to which conceptions, practices and the politics of national security are relevant to understanding dual-use governance in the UK.

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100 Interview with two leading UK synthetic biologists, On file with Author.

101 Interview with UK synthetic biology PI, On file with Author.

In remainder of this chapter, analysis proceeds in four parts, which reflects the discreet policy-generating forums and process which have given rise to dual-use governance activities directed at the field of synthetic biology. In the first section there is an examination of how synthetic biology was identified as a dual-use techno-science by European and UK funding Organisations, as early as 2005. In the following two sections governance activities directed specifically at the issues of dual-use technology and dual-use research are individually addressed in the period between 2006-2010. Finally, there is an analysis of the governance of dual-use techno-science in the period 2010-2012.

### 6.2 Dual-use Concerns on the European NEST Agenda (2004-2007)

As early as 2003, the major EU funding body of NEST identified the field of synthetic biology as area of investment (European Commission 2003). Misuse issues were raised in a 2005 EU high-level report - and received the lion's share of commentary in the section of the document on potential risks associated with the field. The document would prove to be indicative of an emerging problem framing of dual-use issues which was informed by EU experiences with genetic modification research and technology. It was argued within the document that synthetic biology research and technology was comparable to, or an extension of, existing genetic modification practices. This claim extended to assertions about the way the field would be made subject to existing governance regimes. The report states:

> '*In terms of risks, abuses and safety measures, it is not obvious that there is any aspect of synthetic biology that is qualitatively different from the way such issues apply to biotechnology and genetic modification, aside from the far greater capacity for manipulation and control that synthetic biology will afford*'(European Commission 2005, 18).

Even at this early stage, however, it was becoming apparent within the NEST domain that there might be a need for novel governance interventions (such as industry screening), which would create extra responsibilities for emerging industries which provided increasingly

complex and tailored biological products. Added to this, the document reveals an assumption that discussions of issues, such as dual-use, were likely to be polarised, reflecting a more agonistic type of politics. To this end, the document provides 'for and against' type arguments in relation to potential risks. It also portrays science and technology as both a cause and solution to misuse concerns. The document also reveals a concern about knee-jerk public opposition to the field by stating that:

> '*Any discussion of the potential risks of a technology as powerful as synthetic biology must inevitably sound rather alarming. But it is also important with a new technology of this sort to consider also the risks, and indeed the ethics, of not developing it'*(European Commission 2005, 19).

Analysis of the document reveals two key issues grounded in tensions found within EU NEST politics which continue to be reflected at both European and national level. The first is the understood need to reassure the public in relation to concerns which are yet to manifest as manageable risks. The second is the absence of capacity to pre-emptively address, rather than just discuss, dual-use issues, in a mandated political process - despite increasing pressures on relevant industry, funders and scientific community to engage in such processes.

In relation to the latter point, it is worth noting that dual-use issues entered European NEST ethical discourse on the back of US discussions of the field of synthetic biology. In 2004, the misuse scenarios circulating in policy circles and the press were American rather than European- as were potential models of oversight. The 2005 European Commission report identified the issue of bio-warfare, bio-terrorism as well as bio-hacking as relevant dual-use scenarios. However, there had been little indication that the UK security community were taking such issues seriously enough to warrant significant state intervention in the name of national security in the near term at this time;[102] nor were there organic community initiatives

[102] Instead emphasis had been placed on moderate expansions of Law enforcement responsibilities to engage with CBRN misuse concerns against labs, and the need for the scientific community to

within the emerging synthetic biology community in relation to the dual-use issue. Indeed the European synthetic biology community was yet to materialise (Molyneux-Hodgson and Meyer 2009) and there were no publicly known EU based amateur bio-hacking communities.

This meant dual-use issues existed as a potential societal anxiety, but it seemed unlikely that the issue could be converted into a quantifiable and manageable risk in the near term. In this respect, the 2005 NEST document demonstrates that in a European context there existed a type of over-hang in which security concerns, along with other risk and ethical concerns associated with synthetic biology, were being foreseen, which appeared to outpace the emergence of institutional capacity to assess and address these issues**.**

The first major European investigation which considered dual-use issues associated with the field of synthetic biology was a 2 year EU-FP6 funded project called 'SynbioSafe'. The primary purpose of the SynbioSafe project was to '*stimulate a debate*'[103] on the safety and ethical aspects of synthetic biology. The project included engagement with the scientific community at the S.B3 event, public discussion, consultation with synthetic biology experts as well as the production of a series of academic materials on the subject - some of which were published in leading science journals such as Nature. This then suggests the early incorporation of dual-use concerns into the European ELSI agenda. In the following section there is an examination of the extent to which these activities at European level contributed to the generation of UK ELSI initiatives directed at dual-use issues.

### 6.3 From Europe to the UK: Dual-Use Techno-Science on the ELSI Agenda (2006-2008)

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demonstrate the development of infrastructures of self-governance in relation to the dual-use issue from as early as 2003 to prevent the politicisation of the issue

[103] http://www.synbiosafe.eu/

Shortly after the announcement that the BBSRC were to invest into the field of synthetic biology the BBRSC commissioned research into ELSI issues entitled '*Synthetic Biology: Social and Ethical Challenges'* (Balmer and Martin 2008). The report was drafted by scholars based at the University of Nottingham. Martin already had an interest in engaging in bioweapon and biosecurity issues and also contacts with other UK based scholars who had been following the US dual-use biosecurity discussions.[104] The report identified three major misuse scenarios under discussion within the US, specifically bio hacking, the development of new weapons by states, and bioterrorism. The report found that there was a:

> *'require[ment for] a thorough review of existing controls and regulations, and the development of new measures, particularly relating to biosafety, environmental release and biosecurity'* and further to this that *'A robust governance framework must be in place before the applications of synthetic biology are realised'* (Balmer and Martin 2008)

These sentiments certainly chimed with the 2005 EU NEST report. However, the report also reveals emerging tensions within the UK ELSI politics relevant to understanding scope, nature and feasibility of dual-use governance within the UK. In the following section there is an examination of how US dual-use concerns were imported onto the UK ELSI agenda.

The first impact that the US governance discourse had in Europe was to raise the dual-use issue on the ELSI agenda. Within the US, concerns about the prospect of terrorist use of gene-synthesis technology had spread to the broader field of synthetic biology. This spread was due, in part, to the US institution relationships between emerging gene-synthesis capabilities and the emerging synthetic biology community which was galvanised by the involvement of social scientists associated with SynBERC. This situation had resulted in the field of synthetic biology being subject to dual-use concerns to a greater extent than any other contemporary techno-scientific field. The UK discourse inherited these concerns. This was

[104] Including Filippa Lentzos, and Paul Nightingale, who had both been following biosecurity issues since at least the mid 2000's, and had ties to the Science Policy Research Unity at the University of Sussex.

despite the fact that the UK lagged behind with regard to national gene-synthesis capabilities and that the European synthetic biology community and gene-synthesis industries were both in their embryonic stages. This, added to the fact that synthetic biology was the first techno-field to be the subject of European dual-use discussion, suggests it would have been unlikely that these issues would have emerged in Europe without influence from developments within the US.

These discussions certainly created fresh impetus within some institutions as well as external political pressures for research councils and funding bodies to engage pre-emptively with discussions about the dual-use issue despite the absence of the manifestation of 'problematic' research in a UK context. US experiences also had another more subtle, but equally important impact on dual-use discussions in the UK. This relates to how the issue was framed and expectations about how the issue would be governed. In a UK context, dual-use concerns were a new addition to the type of concerns raised by publics and stakeholders in relation to new and emerging technologies. Traditionally (non-medical) ELSI biotechnology issues fall into two general categories. The first are related to defining, agreeing and managing risks (here referred to as 'risk' issues). These issues involve activities by institutions such as the HSE or other secondary regulators. The second set involves more ethical reflections about the relationships between novel science and technologies and 'humanness' or 'society'. These latter societal concerns such as 'playing god' are usually understood to require a philosophical rather than physical remedy. Risk discussions, on the other hand, tend to result in the generation of concrete societal problems which are understood to require immediate risk assessment activities of some kind.

It is conceivable that dual-use issues could have been discussed as an 'ethical' rather than a 'risk' issue within this document and the UK ELSI discussions which followed. Such an

assertion is supported, when one considers attitudes of some leading scientists in the field, who make the claim that any science and technology can be considered 'dual-use', and so does not constitute a risk that can actually be addressed through governance[105]. As it transpired, dual-use issues were understood to fall into the former category in early European and UK reports.

The fact that US discussions had adopted this risk framing, and that communities were in policy focused political processes, certainly contributed to this 'risk' framing emerging in the UK. However, in contrast to the US, there was at this point no synthetic biology community and no major initiatives underway to assess or co-ordinate a response to dual-use concerns associated with the field.

The BBRSC report then signalled the establishment of a dominant dual-use governance logic, which was forward-looking in the sense that new institutions discussed potential dual-use issues which were yet to materialise. However, in the absence of any substantive promises of financial and institutional support for new political processes of collaborative policy development, it was also deeply *ad hoc* and incremental. This was in the sense that it was assumed that response would take the form of a 'patch-work' (Kelle 2012b), which reflected discreet institutional rationales, rather than involving new forms of collaboration politics as part of a co-ordinated policy response. With these assumed political realities in mind, it is unsurprising that Balmer and Martin pragmatically called for engagement with education as a first step in the development of dual-use governance regime, which at the time appeared both dimly conceived and politically contentious. Such recommendations chimed in with educational and awareness-raising initiatives that were been favoured at this time within the UK by intuitions such as the FCO and aspects of the scientific community. This was in the

[105] Interview. UK scientist, on file with author.

context of the growing significance of education and awareness raising within the context of the BTWC.

This situation reminds us that developments within the ELSI discourse were tightly inter-wound with the assumed realities in other domains. In the following sections the nature of this relationship, as well as the role of the rhetoric and politics of security are put under scrutiny. Specifically there is a need to consider how developments within each of the four domains of dual-use governance can be understood to have contributed to, or else impacted upon, the process by which initiatives have emerged and how this relates to theoretical questions about the politics of security.

### 6.4 Dual-Use Technology and the Politics of Security (2006-2010)

So far it has been demonstrated that between 2005 and 2008 broad aspects of the techno-science of synthetic biology were being discussed with reference to dual-use potential in European ESLI forums. This ranged from bio-terror to bio-warfare concerns relating to a broad swathe of foreseen developments in synthetic biology. The potential need for controls in response to such developments had also been raised. This was understood to extend beyond genetic material, conceivably including proteins involved in biochemical expression systems. At this time, it was also suggested that 'controls and regulations [could] be imposed on 'parts suppliers'(European Commission 2005, 18). Likewise in 2009, the European Group on Ethics expressed concerns related to the potential of state as well as sub-state misuse of synthetic biology technologies and called for systems of oversight that could address both of these issues, under obligations laid under the BTWC (European Group on Ethics 2009, 52). Added to this, various bioweapon experts and committees, largely from the US, had suggested that the foreseeable proliferation of synthetic biology technologies could aid the development and use of novel weapons in the foreseeable future (Tucker 2012).

However, the only specific technology, which was subject of policy discussions at government level within the UK during this period, was gene-synthesis technology. This raises questions about why this specific field of technology has been subject to action and why broader aspects have not. In the following section this issue is examined.

### 6.4.1 Early Government Responses to Dual-use Gene-synthesis Technology (2006-2009)

In 2006, the first significant biosecurity concern to emerge in a UK context were raised by an article that appeared in the Guardian. The article outlined how a journalist had ordered a segment of smallpox *Variola* DNA from a UK biotechnology company. (Randerson 2006). The segment, which encoded for part of the protein coat of the *Variola* virus, [106] was duly dispatched to a private address in London.

It was argued in the article that the order should have raised alarms at the company. The article also connected its findings with trends in science and technology which were making the synthesis of genome-length sequences from short oligonucleotide sequences more commonplace. This then, for a while at least, suggested the prospect of public pressure on government to toughen up on the regulation of the gene-synthesises industry. However, in the absence of political and public interest, the Guardian-orchestrated 'scandal' did not become a means to instigate a broader review of the dual-use biotech issue or indeed bleed into concerns about the misuse of scientific research, in relation to pathogens or contemporary poster-boy fields such as synthetic biology.

[106] The DNA code had actually been modified slightly before it was ordered, as to avoid breaking laws covering select-agents. However the modification would not have been significant enough for the company to argue that the modification undermined their screening processes (if such processes had been in place).

The primary publicly-known response from government came in the form of an interdepartmental meeting held by the Department of Business Innovation and Skills which addressed '*The potential for misuse of DNA sequences (oligonucleotides) and the implications for regulation*' (Department of Business Innovation and Skills 2006). The focus of the meeting and the report that followed was upon the immediate feasibility of misuse by small terrorist groups. This pragmatism meant that the problem framing was very restricted in comparison with discussions occurring in some aspects of the European NEST domain at this time, which, although largely constrained to the threat of bioterrorism, were still looking beyond immediate industry capabilities. The meeting focused on risks which were understood to be 'immediate' rather than feasible in the long-term based on hypothetical developments within national biotechnology capacity or scientific research. Such perspectives were also informed by assumptions about the central role of existing biosafety and biosecurity paradigms in preventing misuse. Within this understanding, existing governance systems were expected to maintain vigilance and respond to novel risks at the point at which they appeared more immediate. This idea was also supported by the claim that standard operating practices within research institutions and industry and similar ethical systems '*can be used to respond quickly to changes in technology*' (Department of Business Innovation and Skills 2006).

Such framing impacted on the aspects of the gene-synthesis technologies which were made subject to dual-use governance at this point in time. First, it was more established practices of shorter *oligonucleotide* sequence synthesis, rather than the emerging gene-length sequence industry that was the focus of attention. This meant that concerns about terrorists ordering gene- or genome-length sequences from specialist firms were not attended to. This issue would spark a European industry response only two years later as the European gene-

synthesis continued to develop. Second, while there was an appreciation '*technologies will advance such that pathogenic organisms could be constructed or (more likely) be modified more easily*' (Department of Business Innovation and Skills 2006), no specific developments were identified, nor was there discussion of the need to identify these developments. This meant that no specific political process was put in place to respond to such issues, instead it was stated that '*key organisations [were] to alert Government if they become aware of any significant advances which might lead to major technological changes and thus to increases in risk'* (Department of Business Innovation and Skills 2006). In the period between 2006-2008 there were minimal activities within the HSE, FCO, Home Office and National Counterterrorism security office directed at dual-use synthetic biology or dual-use technology more generally which was, in the main, confined to organising and attending seminars and keeping a watching brief on fields such as synthetic biology.[107] However, this did not translated into policy initiatives on the part of these institutions. For example, the HSE produced a small horizon scanning piece on the broader field of synthetic biology in 2007, but this did not address misuse issues. Added to this FCO, Home Office and National counter-terrorism security office policy initiatives were also slow to emerge**.** For example, it was not until 2012 that the National counter-terrorism security office began seriously considering the development and implementation of dual-use awareness-raising and educational programmes outside of military research facilities in relation to life-science research.[108]

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[107] In relation to the HSE see Memorandum submitted to the House of Lords Select Committee on Intergovernmental Organisations (Health and Safety Executive 2008). In relation to the FCO see evidence submitted to House of Commons Foreign Affairs Committee (Foreign and Commonwealth Office 2009) also were keeping a watching brief on synthetic biology through attendance to the Synthetic Biology Policy Co-ordination Group from 2007 to 2009 (on file with Author)

[108] Presentation from NACTSO representative at Responsible Conduct of Research for Scientists and Engineers: Twin International Meeting, The Norcroft Conference Centre, University of Bradford, Bradford, UK July 2012. On file with Author.

This is particularly surprising as education had been a favoured response to other 'dual-use' technology issues (i.e. firearms and chemicals) within that organisation (Home Office 2009, 2:2 at 12.19 ). There was also minimal interest from the Ministry of Defence, who delayed an investigation into potential threats and opportunities associated with the field which had been agreed in 2006.[109] This lack of engagement was also reflected at parliamentary level, with minimal discussion of the dual-use issue more generally in this period, with the issue only raised on the periphery of international non-proliferation, laboratory biosafety and public health issues in debates within various parliamentary committees, often by aspects of the scientific and academic arms control communities.[110]

In this period, there is little evidence of systematic searches for new risks, as well as an absence of investment into the development of scientific criteria for the identification and evaluation of novel dual-use risks in relation synthetic biology technologies. The absence of engagement, as well as clear direction, would be revealed most clearly in coming years, as the gene-synthesis industry emerged.

### 6.4.2 The rise of International Industry Associations in Dual-use Technology Politics (2007-2010)

In 2007, several industry scientists and technologists with an interest in the emerging European gene-synthesis sector met in Heidelberg, Germany in order to discuss the potential for the establishment of some form of synthetic biology industry association. The foundation of the ISAB in early 2007 was underpinned by a number of political drivers. First, there was

[109] Plans for this investigation were picked up and reported publicly in a Parliamentary Briefing Paper (POST 2008, 3) However, the plans were shelved and that particular enquiry never took place. (Confirmed by Email correspondence with the intended author report, on file with Author).

[110] For example (Health and Safety Executive 2008) at an Inter-governmental organisations committee meeting, House of Lords. (Foreign and Commonwealth Office 2009) at Foreign affairs committee meeting, House of commons

a growing interest within European industry in the field, which created a need for novel forums for pioneering biotech companies to collaborate. Second, there was an apparent need for industry to pre-emptively engage with risk issues associated with the technology in the context of growing European and funder interest in the field of synthetic biology. This need stemmed from historical, European experiences of societal resistance to GM technologies, as well as more recent US experiences in relation to biosecurity issues. Third, the novelty of the field meant that the government was only in the early stages of assessing its potential regulatory implications of increasing gene-synthesis capacities, creating uncertainty for the industry. While indications had been given that the existing regulatory framework was adequate, it seemed increasingly likely that these frameworks would require review and amendment in response to the emergence of the gene-synthesis industry at national and European level.[111] In response, a decision was made to engage in some form of activity to which would pre-emptively address the risk issues associated with the field, this activity from the outset was understood to involve public engagement, risk management activities and advocacy in relation to regulators. The politics surrounding the emergence of the policies are significant for understanding the politics of security surrounding dual-use technology issues, and are now addressed.

The IASB held a workshop in April 2008 in Munich. The workshop brought together industry representatives, social scientists, as well as European public health and biosecurity experts. An important addition to this group was also Steven Maurer, who had already had first-hand experience of the development of biosecurity initiatives in the US in relation to the field of synthetic biology. The workshop agreed a work-plan which was published on the ISAB website and has since been widely cited in European policy material on synthetic

[111] Interview, with ISAB representative. In a UK context, while there has been a re-assertion that non-infective genetic material was not subject to Biosafety and Anti-terror laws, there was no guarantee that this position would be maintained, genetic material was also covered under Export Control regulation.

biology. This work package included six sets of activities these were: the harmonization of screening practices, utilizing closed online industry information forums; co-operation with the Goldman School of Public Policy in the Building or a virulence factor database;[112] the publication of an article on the 'status quo' of synthetic biology; the establishment of a policy steering group; Publication of IASB member screening practices*;* as well as engagement with other stakeholders internationally. Since this time, however, there have been modest activities in relation to these aims, constrained in the main by the absence of resources.[113] This has meant that much of the focus of the ISAB has been raising its profile in industry and biosecurity forums, as well as courting government investment. For example, work on the development of new screening databases and software has been very slow (in both a European and US context). Added to this, there has been little, if any, publicly known work on the harmonization of practices among members since 2009.

This being said, the ISAB has certainly punched above its weight when one considers its political impact in Europe. Not only has the this actor behaved as a successful securitization actor in relation to the issue of gene synthesis, it is also likely that this may set a broader precedent in European politics in relation to other industrialising aspects of synthetic biology. Largely insulated from the antagonistic politics of the NEST domain, the IASB instigated a political process which allowed industry to rise as the predominant developer and implementer of security policy directed at the gene-synthesis issue in relation to the scenario of terrorist misuse. This helped secured 'industry screening', rather than other forms of intervention, as a central part of the response the scenario of terrorist misuse of synthetic

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112 The idea behind this data-base is can used to screen against dangerous 'genes' encoding for virulence factor proteins, as opposed to screening from whole viral genomes. This was in order to make sequencing more focused on dangerous aspects of viral genomes.

113 The ISAB composes or a core 'staff' or around 5 or 6 individuals who work on the project in their spare time, They have a very modest annual spend of up to approximately 10,000 Euro a year. (interview with ISAB founding member, on file with Author).

DNA. However, the existence of the ISAB in its own political niche has come with a cost, which, for the foreseeable future, will likely limit the institution's ability to further develop and implement policy. Specifically, the ability of the IASB to be more reactive to the dual-use challenge presented by gene-synthesis technologies has meant that for several years 'it has ran beyond' the interests of the European institutions from which it needed support. If anything this group's activities have, at times, been used as a 'public bolster' by departments against the need to take action as the work of this group was often referenced within European NEST forums without the suggestion of government support or viable policy alternatives at this time (House of Commons: 2010, 55).

This being said, in the following section it becomes clear that the ISAB has likely cemented the position of similar institutions in European politics in the coming years. This, in essence, means that even if the IASB were to quietly fold in coming years - taking the existing policy channel with it - the absence of state activity in this area, coupled with the activities of this group, has resulted in the emergence of political space for such organisations within the NEST, anti-terror and biosafety domains. This looks likely to facilitate the emergence of similar actors within industry who would likely mirror the approach of this group.

### 6.4.3 Conclusions: The Securitization of Dual-Use Synthesis Technology in the UK (2007-2010)

In the UK, the domestic gene-synthesis industry is small, with a handful of companies providing tailored gene-synthesis products,[114] there is no data publicly available about how many of these companies there are; how many are signed up a screening standard or how many implement biosecurity policies. Added to this, the nature of the market is also unclear. It is likely, for example, that many UK-based researchers also rely on imports from the US,

[114] For example, http://www.bioscience.co.uk/products/gene-synthesis-service-genemaker

Germany and, increasingly, China.[115] In the UK there are no clear channels of policy development in relation to the gene-synthesis issue at a national level, with no institution having a clearly defined remit in this regard.

During this period, the UK government, the HSE and FCO, as well as the Department of Innovation of Skills who grant dual-use export licences, adopted a wait and see approach in relation to scientific and technological development. Existing biosafety and ethical governance structures were appropriated or ear-marked as *de facto* biosecurity systems - however there is little evidence that they were ever actually utilized for the development of secondary securitization.

The process of organising the interdepartmental meeting is an example of successful primary securitization as the meeting constituted a contrived political process which allowed an issue to be made 'governable' in the name of security. This meeting also reflected the predominance of a framing of the dual-use technology issue which was constrained to those issues which could conceivably by addressed existing biosafety and export control systems. Thus while the dual-use issue was making it on to agendas, there was no pre-emptive policy development, such as in-depth risk-assessment type activities, or the development of capacities to implement such assessment. Instead the dual-use issue continued to exist in the main as an under-addressed 'ethical' issue on NEST agenda, rather than a risk issue requiring action in the biosafety or anti-terror domains. It is clear that this creates an environment which is unfavourable for the emergence of pre-emptive policies directed at identifying a responding to potential dual-use concerns. It is also worth reiterating at this point that the majority of initiatives discussed in this were not designed to address the prospect of state-

[115] The tendency for scientists to choose cheap, and reliable products regardless of where they are produced, or the bio-security policies that the companies adhere to, was a re-occurring theme in my discussions with UK scientists.

level misuse and tend to ignore more forward-looking concerns about broader trends within emerging biotechnology. This issue is returned to towards the end of the chapter. In the next section the emergence of activities directed at dual-use research within the field of synthetic biology in this period are now addressed.

### 6.5 The Security Politics of Dual-Use Research (2007-2010)

By 2007, growing interest at US an EU level in synthetic biology had motivated a BBRSC led funding initiative. The initiative involved the establishment of seven new research networks in synthetic biology designed to foster an interdisciplinary synthetic biology community within the UK. From the outset, the was a requirement for scientists to engage with ethical, legal and social issues when designing and carrying out research (BBSRC 2008a). There was also a level of optimism expressed in relation to the ability of the synthetic biology community to engage pre-emptively and responsibly in managing the societal impacts of the field. In the public announcement of the Network Initiative, it was stated that:

> *'We think it is important that scientists and research funders are aware of the wider social and ethical issues surrounding synthetic biology. From events that we and others have held recently, we are confident that UK scientists will address such issues when planning and carrying out research involving synthetic biology'*(BBSRC 2008a).

Such optimism was unsurprising for several reasons. First, there was a pre-existing faith in the capacity of the existing regulatory framework to address any risks that emerged related to the field of synthetic biology. This suggested that the scope of the community responsibilities were limited to public engagement or helping to facilitate the response of existing regulatory institutions such as the HSE to the issue.[116] It was also assumed that ELSI researchers (mainly social scientists and ethicists) could contribute to the evaluation of ethical concerns

[116] As was stated at a regulators meeting organised by the BBSRC at the time '*The overriding message from advisory committee members was that none of the questions and hypothetical scenarios suggested a paradigm shift that would necessitate amending the UK's regulatory framework. However, some issues may require particular attention within the framework'.* (BBSRC 2008b, 2)

as well as risks in the context existing regulatory, funding and research ethics review processes.[117] This was in the context of rise of synthetic biology as a 'hot topic' within policy and ethics research centres following US debates. The BBSRC Network model held the promise that the interest of these scholars could be channelled in the related tasks of integrating societal demands and concerns into the practice of research and reassuring the public in relation to the fledgling field. The research councils and regulators were also keen to emphasise the role of the synthetic biology community and ELSI researchers for another reason. This was because there were concerns at this time among the funding institutions that there was a risk that security, and particularly safety concerns, about emerging fields would lead to a public back-lash before novel applications could even be developed. In a publicly available report on a meeting between the research councils and regulators, violent imagery was used to describe the threat posed by public and regulatory backlash against the field, stating that:

> *'There was agreement [among those that the meeting] on the importance of ensuring that unnecessary regulation does not 'strangle at birth' the potential benefits of synthetic biology products; and that regulatory procedures should be realistic and proportionate, not burdensome.*'(BBSRC 2008b, 4)

During this period, research funding institutions mobilised to ensure a central role (for themselves) as well as the emerging synthetic biology community in the political process of policy development directed at ELSI issues associated with the field. This involved collaboration with institutions such as the HSE, the Department of Innovation and Skills and law enforcement agencies in the context of existing regulatory structures. The question remains, however, in relation to the extent to which these activities constituted primary securitization, or fostered secondary securitization. In relation to the first question, there was

[117] At the BBRSC regulators meeting it was also stated that '*Research applications go through local ethics committees and research council ethical review processes in addition to their review through regulatory committee reviews. A view was expressed that constitution of these committees should be considered to ensure their capacity to manage this risk. Consideration of Ethical Legal Societal Issues (ELSI) is also an important part of the new synthetic biology networks*'. (BBSRC 2008b, 3)

early consensus between the scientific community and other regulatory institutions that the scientific community would take the lead in relation to governing dual-use research. This was based on consensus which had emerged as early as the Parliamentary '*Scientific Response to Terrorism'* report writing process (House of Commons Science and Technology Committee 2003). Therefore, this was an attempt to encourage secondary securitization within relevant communities, who were expected to play a role in the identification and governance of dual-use issues as part of a system of identifying and responding to dual-use risks. This idea was not challenged nor were there moves to develop security policy beyond these earlier vague agreements. This, essentially, meant that the there was still a space for the synthetic biology community to behave as a secondary securitization actor, within the remit of the vague agreements made in 2003. In the following section there is an examination of the extent to which the scientific community (including associated ELSI scholars) took on this role in relation to the field of synthetic biology.

### 6.5.1 Community Self-Governance (2008-2010)

UK scientific institutions can be understood to have responded to dual-use concerns in two ways. The first is through the development and implementation of policies to enable the identification and management of certain types of dual-use risk, particularly in relation to theft and diversion, in collaboration with law enforcement (which primarily involved education and awareness raising initiatives within the community). The second set of activities, were intended to frame and communicate the dual-use issue to wider society. Most of the activities of the scientific community are easily separated into these two categories. For example, the Report from the Royal Academy of Engineering (Royal Academy of Engineering 2009), is obviously primarily designed to frame and communicate risks to the public. Likewise, educational and awareness design activities engaged with by the Royal

Society and under the aegis of the Wellcome Trust project '*Building a sustainable capacity for dual-use bioethics*' are primarily, designed to contribute to a system of identify and responding to dual-use risks. In contrast, it is unclear which of these categories ELSI activities conducted under the auspices of the BBRSC funded networks fall into. This is because at different points in time various roles have been ascribed to both the scientists and social scientists that make up this community (See for Example Calvert and Martin 2009). Such confusion stems from long-standing tensions in UK ELSI politics, as well as the need for social scientists involved in ELSI governance to justify their own role in the innovation process- to publics, funding institutions as well as the public. In the following section activities of ELSI researchers in these communities is further examined.

Dual-use synthetic biology in the seven synthetic biology research networks…..

As should now be clear, in the early years of the field of synthetic biology there were very limited risk-governance activities taking place within government departments and Royal Society, as well as at community-level in response to dual-use concerns that directly contributed to the emergence of dual-use governance capacity. This reflected a broader trend reflected in recent dual-use discussions about gain of function H5N1 research, which have moved on little from discussion about dual-use research which began nearly a decade ago in a UK context. This is in the sense that there remains an emphasis on the importance of education of publics and scientists, as well as the centrality of review at funding stage. However, there were no substantial technical reviews of the development, implementation and evaluation of these policies during this period by parliament or key departments.

Despite the fact that dual-use issues had emerged on anti-terrorism and biosafety agenda, the prevailing logic was that the dual-use issue did not currently raise problems that required a response, and that institutions could respond to any issues that did manifest *ad hoc*. This

produced a dead policy space between the societal concerns imagined in the BBRSC report as well as the public in the mid-2000s and projected developments in the field over the coming decades. As a consequence, governance responses to the challenges raised by synthetic biology would involve incremental responses within discreet institutions, rather than more forward-looking policy and capacity-building. They would also involve the externalisation of broader societal issues which could not feasibly be addressed through existing regulatory systems, or modest modifications of these systems. Within in the NEST domain, in reaction to this type of approach to science governance more generally, several social scientists active in the BBRSC networks have expressed an interest in more 'up-stream' engagement with the scientific process. In the remainder of this section there is a critical assessment of the aims of these researchers in the networks between 2007 and 2010, the extent to which these aims have been achieved as well as the discernible impact on the governance of dual-use issues.

Writing in 2009, two social researchers central to the UK synthetic biology ELSI community, outlined their preferred model of engagement with scientists, which was held in contrast to more traditional forms of ELSI engagement (Calvert and Martin 2009). They argued that such an approach to engagement required 'collaboration' between social researchers and the synthetic biology community. They argued that such collaboration could involve:

> '*Scrutinizing the assumptions underlying the research of both natural and social scientists, and challenging habitual ways of thinking among both groups*…. Which could help '*create a more ethically acceptable and socially useful field of study and application*' (Calvert and Martin 2009, 202).

These researchers were seeking to engage up-stream in the process of innovation and address potential risks before they emerged. Conceivably, such activities include the instigation of policy initiatives and political processes designed at generating and responding to foreseeable

risks; including those raised by the dual-use issue. Such sentiments reflected the approach to ELSI engagement which was being attempted at Synberc at this time.[118]

There were, however, from the outset, two limitations on the potential scope of impact of these activities in relation to the development, implementation and politics of dual-use governance.

The first related to the primary focus upon engagement with the scientific community, based on the view that this would have knock-on effects later in the innovation process. This then meant that activities primarily focused upon engineering ethics (or reflexivity) into scientific research, as an exemplary field, rather than directly at changing prevailing norms and practices within institutions involved in the funding of translational research; the implementation of risk governance directed at industry such as the HSE; or within biotech industry. This essentially meant that while there was some engagement 'up' the innovation process, there were less activities directed at impacting upon the politics of risk governance 'down' the research translation process. For example, in scenarios where scientific research is utilised by industry to generate novel technologies by investors from outside of academia. Such a position was not unreasonable, bearing in mind the absence of interest from key regulators during the early period of the field's development. Instead, the researchers were forced to adopt pragmatic aims – which combined their pre-existing sociological interests in the formation of techno-scientific fields and the availability of the growing synthetic biology community as a more accessible (if limited) agent of change.

[118] Indeed, scholars from Synberc were asked to present on their experiences at a meeting which launched a UK ELSI manifesto document for discussion at a meeting held at King's College on the 19th June 2012.It is worth noting that this meeting provided a public froum for Gaymonn Bennett to express his explanation of why social scientists had not being successful in achieving their goals at Synberc; as well as why his boss Paul Rabinow had to step-down as leader of the Synberc ELSI thrust.

The final issue related more specifically to the framing of the dual-use issue adopted by prominent members within this community who have stated publicly that, the forward-looking dual-use concerns do not constitute an immediate risk and are a distraction from other, more pressing, issues which require attention, such as the democratic deficit within the innovation process. For example, Marris and Rose (2012) argue that most discussion of dual-use and other risk issues is based on technical ignorance about the current capabilities and practice of the field of synthetic biology and that '*Commentators instead focus on potential reckless use or misuse, overestimate the pathogenic possibilities.…*'. They argue that this is an:

> '*Example of speculative ethics that distracts us from less exciting but more pressing questions. What are synthetic biologists actually doing?* How *easy, or difficult, is it proving? What applications are they realistically going to develop in the short to medium term? What is their intended purpose, and to what extent could these contribute to the public good?*''. (Marris and Rose 2012, 28–29)

This then suggests a mismatch between the optimism expressed by social scientists within this community as well as the research councils about the role of ELSI activities in risk governance and the realties within the research networks. Indeed this discrepancy motivated Edwards and Kelle to examine the relevance of ELSI activities within the UK synthetic biology networks to the prospect of dual-use education. They found minimal attention to the dual-use issue and minimal activities with a discernible impact on the emergence of education initiatives (a widely favoured strategy for improving risk management) (Edwards and Kelle 2012). Further investigation into the online record of network activities reveals that the conceivable impact of social scientists within this network on the emergence of a dual-use governance regime directed at synthetic biology research was, in the main, limited to raising awareness within the synthetic biology community about the work of social scientists as well

as societal concerns and relevant governance frameworks.[119] Interviews with PIs also revealed that awareness and substantive knowledge in relation to the dual-use issue also varied greatly, reflecting the absence of systematic education and awareness-raising in this field. However, there is also some evidence of increasing interaction between the broader synthetic biology community and the broader BTWC arms control regime.[120] This suggests that the support provided by the network ELSI funding has helped foster some tentative novel collaboration between the UK synthetic biology community and those with an interest in dual-use issue.

### 6.5.2 Conclusions: Governance of Dual-Use Aspects of Synthetic Biology Research (2008-2012)

In relation to the question of who securitizes on the issue of dual-use research within a UK context, the situation remains largely up in the air. While the UK synthetic biology community had a remit (albeit vaguely defined) to implement and develop policy responses to the dual-use issue, such developments were both modest and tentative in this period. This was underpinned by the absence of institutional support and engagement, specifically the FCO and HSE. However, this was also underpinned by the pre-dominance of a norm within the broader UK synthetic biology community, which downplayed the significance of dual-use issues as they were understood to constitute more long-term, or far-fetched concerns, in the pursuit of more pragmatic aims in relation to the field. This then demonstrates the absence of secondary securitization processes within this field. Analysis has also demonstrated that it is

[119] Based on examination of network website and publicly available meeting material, discussions and interviews with prominent members of the ELSI community as well as project reports. On file with Author

[120] See for example: (Dando 2010) Jane Calvert ( A social Scientist involved with the synthetic biology networks) was a speaker at a side event at the 2011 review conference, along with other prominent members of the European and US synthetic biology ELSI community. Several other events addressing dual-use issues have also being organised through the UK based ESRC Genomics network http://www.genomicsnetwork.ac.uk/esrcgenomicsnetwork/events/.

unlikely that the dual-use issue will stimulate significant anticipatory risk governance activities in relation to synthetic biology in the foreseeable future. This situation has also been underpinned by an absence of support and initiatives within the anti-terror and biosafety domains in relation this issue. As a consequence, the politics of security surrounding research within the UK remains one that is dominated by institutions in which the issue is marginalized. These findings, along with developments in relation to gene-synthesis technologies provide the context of the final political process which is now examined.

### 6.6 The Prospect of Re- invigorating Techno-Science Governance (2009-2012)

In the period between 2009 and 2012, a coalition of representatives from UK biotech industry, leading scientists, as well social as scientists associated with key synthetic biology research centre (in particular those from the Centre for Synthetic Biology and Innovation based at Imperial) advocated greater support for the domestic gene-synthesis capability as part of improving UK research and translation capabilities,[121] as well as basic and translational research within field.[122] In 2010, the House of Commons Science and Technology Committee held a meeting on the topic of bioengineering and were convinced that there was:

> '*a widespread consensus that developing a national DNA synthesis capability would put the UK at the forefront of synthetic biology translation and what some consider to be the next industrial revolution'* (House of Commons: 2010, 44).

Further to this, it stated that**:**

> '*Such is the current, and future, value of DNA synthesis that the UK cannot be found to be in a position where this capacity is sub-contracted. A national initiative to develop cheaper, faster, longer, high-fidelity DNA synthesis would put the UK firmly at the front of this new industrial revolution. [...] We should not be put in a position*

[121] This perspective was supported with reference to recent industry investment in UK gene-synthesis translational research to the value of £2.5 millon

[122] This built in part on coalitions built through the Synthetic Biology Policy Co-ordination Group, based at the Royal Society, which functioned from around 2008-2011.

> *where we try to build a new industry on top of out-sourced foundations.*'(House of Commons: 2010, 26)

To this end, the report suggested that the Technology Strategy Board should manage a national initiative to develop the field. Within the following 2 years, UK institutions received approximately £25 million in investment, the majority of this funding focused on the development of foundational technologies, as well as the translation of synthetic biology research (BBSRC 2012).

Scientists and social science researchers from the Centre for Synthetic Biology and Innovation gave evidence as part of the bioengineering drafting process and referred to the issue of dual-use technology. Their comments in evidence, as well as a report from the Synthetic Biology Co-ordination group that followed, demonstrated continued optimism:

> *'Overall our view is that further research and continuing discussions are needed between SB practitioners and national and international regulators to develop an effective governance framework that will mitigate risks without imposing an undue burden of regulation that hampers the innovation pipeline, yet which ensures justified public confidence in the safety and security issues. Some of this work will be conducted by BIOS researchers within CSynBI, working with the Royal Society.(House of Commons: 2010, 4)*

Such sentiments were also expressed in a report produced by the Synthetic Biology Technology Strategy Board:

> *'It will be crucial, as synthetic biology progresses, to continue developing a robust regulatory and enforcement regime involving scrutiny, evaluation and modification of existing regulations to address issues such as indirect, delayed, and cumulative long-term effects, including accumulated effects of approvals for different organisms; and appraisal of risks which consider how the technology will be used in practice, in real-world conditions. The latter includes the potential for 'dual use' at a time of increasing global uncertainty'*(UK Synthetic Biology Roadmap Coordination group 2012, 21)

Such rhetoric certainly suggests a continuing support for the development of anticipatory systemic risk governance systems. However, bearing in mind the recent history of the field of synthetic biology, specifically with the slow and pragmatic response of regulatory bodies, the government, as well as the synthetic biology community, one must question the current

feasibility of such an endeavour even in relation to existing gene-synthesis technology and practices of innovation. In relation to the dual-use issue in particular, the recent characterisation of the dual-use issue as an 'ethical' rather than 'risk' issue by prominent scholars at LSE, suggests that the dual-use issue is likely to receive much less attention within this institutional context as a target of new secondary securitization initiatives within the NEST domain.

### 6.7 Conclusions

Within securitization theory, a key focus has been upon the questions of who securitizes, how, what, and under what conditions and with what effects. Within this chapter each of these questions has been attended to, and it is worth recapitulating some key points before further discussion in the comparative and conclusive chapters.

With regard to the question of who securitizes in relation to dual-use issues, it is apparent that institutions such as research funders as well as those in charge of laboratory biosafety and biosecurity are widely understood to be of central importance in the oversight of dual-use issues. This role has been secured through two forms of activity. First, institutions such as the HSE as well as member of the ELSI community have asserted the role of existing biosafety regulatory systems, education and awareness-raising initiatives as central to the governance of existing dual-use concerns as part of parliamentary reviews of the area. Second, in relation to oligonucleotide synthesis, these institutions have collaborated in the generation of political process in which these existing systems were ear-marked as key aspects of biosecurity responses. Another key actor has been the ISAB, which has taken a pro-active approach in defining policy options and implementing policy initiatives directed at the synthesis industry. Generally speaking, however, government departments have adopted a wait and see approach

with regard to dual-use concerns and have placed faith in the idea that scientific institutions and industry are in a position to identify and respond to dual-use concerns.

In relation to the question of what has been securitized, it is clear that, apart from initiatives within the gene-synthesis industry, those aspects of synthetic biology which have been made subject to security governance are those which can conceivably be addressed through existing systems of biosafety and biosecurity governance. With regard to the consequences of these activities, the extent to which dual-use issues have actually, or are likely to be made subject to risk management within these systems, remains unclear. This is because there is absence of a designated institutional capacity to resolve dual-use dilemmas should they emerge in a UK context, as well as an absence of specific and national wide conventions to identify and respond to dual-use research of concern. Specifically, with relation to the synthetic biology NEST domain, there has also been no significant attempts to identify dual-use concerns specific to the UK field. This, again, reveals an absence of institutional interest in pre-emptively engaging with dual-use concerns which cannot be addressed through the application of existing biosafety and biosecurity risk management systems.

In the final two chapters each of these ideas is addressed, as more cross-cutting themes are developed and analysed.

# Chapter Seven: Comparing the Scope, Practice and Politics of Dual-Use Governance within the US and the UK

## 7.1 Introduction

Analysis has revealed key historical moments, institutions, ideational factors and practices which have constituted dual-use governance within the case studies. In the following section these findings are held in relief against each other in order to develop key lines of argument about the scope, politics and practice of dual-use governance. This involves a structured comparison utilising analytical concepts developed throughout this thesis in order to address key research themes outlined in chapter two. A brief overview of these themes, as well as the analytical framework developed to address these themes, is now given.

At the outset of this thesis, it was claimed that the emergence of the dual-use issue on US and European agendas was underpinned by:

a) The emergence of fears about terrorism, in particular bioterrorism, both in public and policy circles, specifically the threat from non-state actors;

b) The dominant assumption about the fast pace of scientific and technological development associated with the life sciences;

c) Changes in the relationship between science and democratic societies. Over the past decade much of the academic literature on the dual-use issue has focused on the question of how to address a conception of the problem of dual-use.

In chapter two it was argued that in order to study the practice and politics of dual-use techno-science governance, it is important to distinguish between four discreet domains of politics. It was suggested that it would be myopic to analyse the manifestation of the dual-use issue within a specific domain which were each understood to comprise of different styles of politics and reasoning. However, carving up of the idea of 'dual-use governance' into four largely discreet domains challenged the stability and self-evidence of the concept dual-use governance. That is to say, while most scholars and policy-makers identified comparable

histo-political context and responses in their description of dual-use governance as part of a web or responses, the question of how these activities relate to each other in the formation of an emerging regime remains largely unanswered. It was suggested at the end of chapter two, that in conceptualising dual-use governance as an emerging systemic risk in governance regime was the first step in addressing this question. The second step required the development of an analytical framework which could incorporate agency, ideational and structural factors into a coherent overview of the political processes that have generated dual-use governance.

This task was addressed in chapter three. The analytical framework that was developed built upon insights from securitization theory. Scholars in this field have been reflecting on the politics and practice of security for over decade and a range of analytical concepts were identified for use in the task in hand. The analytical framework focused on the interaction between agency and structure in the process by which policies emerge, utilising analytical concepts drawn from policy process theory as well as critical discourse analysis to help structure the study of this interaction. This involved the analysis of how actors engage with security politics (including the policy-making process) why and with what effects.

In chapter four, the field of synthetic biology was introduced as an example of an emerging techno-scientific field which has been the subject of dual-use governance. A focal field was required for two main reasons. First, there has been no in-depth study of new and emerging scientific practice and artefacts as the subjects of securitization. Therefore it was necessary to conceptually unpack the process by which framings of scientific fields are generated. Second, as there was an absence of dual-use governance theory within the literature, a narrow and deep focused approach (i.e. a single field) was chosen to enable the development of new theory and hypotheses related to dual-use governance. The field of synthetic biology was

chosen as a focus because it was the field that had been associated most prominently with dual-use concerns. This was important as dual-use governance norms developed in relation to this field may be reproduced in relation to other fields that become embroiled in dual–use politics. Investigation into this field may also go some way to revealing which factors contribute to scientific practices and artefacts being labelled as dual-use concerns. It was demonstrated in chapter five that claims about dual-use problems involve assumptions about governance but also about science and technology. Further to this, it was suggested that the emergence of shared assumptions in relation to a given techno-scientific field are be underpinned by trends in the way in which new and emerging technologies are assessed in modern societies.

In the following sections, concepts, hypothesis and lines of argument (developed in earlier chapters) are used in order to examine the three central focal points identified in chapter two specifically:

- The subject and scope of dual-use governance
- The politics and practice of dual-use governance
- The nature and prospect of national styles of dual-use governance

These central lines of inquiry are now addressed through a structured thematic comparison of the US and the UK. Each of these sections, to varying extents, emphasise the role of ideas, practices and political processes in the emergence of dual-use governance.

### 7.2 The Subject and Scope of Dual-Use Governance within the UK and the US

This focal point of analysis involves identifying which aspects of synthetic biology have been constructed as presenting a dual-use threat and the relationships between these threat constructions and pre-existing discourses and practices. It is worth briefly distinguishing

between the ideas of 'subject' and 'scope' here, as this distinction is of some consequence. 'Subject' refers to the delineation of those specific scientific and technological artefacts and practices which, though political processes, have been framed as part of governable problems. In contrast, questions of 'scope' place greater emphasis on the idea that certain lines of research, materials, technologies and practices have been made subject to dual-use governance and others have not. This distinction leads to questions about the nature of the frames which have been applied to scientific practice and artefacts in dual-use discussions within both cases. This later discussion emphasises the extent to which the identification of dual-use problems is heavily dependent on histo-poltical context. This dovetails into questions about the political processes which have impacted upon questions of 'subject' and 'scope' of dual-use discussions in national contexts.

A key finding within this thesis has been that comparable scenarios have been discussed in a UK and US context (see table below). However, the identification of such scenarios by actors are not, in themselves, an indication that these scenarios are been taken seriously as policy challenges. For example, one individual interviewed involved in the DIY bio-movement, tongue firmly in cheek, suggested a scenario in which research into the effect of chicken soup on the immune system could breed 'dual-use' findings.[123] Likewise, a leading scientist, part of the UK synthetic biology community, who also alluded to common misuse scenarios in his interview, expressed the view that '*anything could be dual-use*'[124] in the context of frustrations with public discussions of the dual-use issue. Indeed several scientists interviewed commented on the seemingly arbitrary way in which dual-use scenarios appeared within the governance and public discourse. Two scientists interviewed also referred to the way in which scenarios were maintained through discussions on ELSI agendas. One even

123 Interview on file with Author: Foundational Amateur Biologist.
124 Interview on file with Author: Foundation scientist in the UK synthetic biology community

went as far as to argue the ELSI and public discourse also generated implausible scenarios which were based on misunderstandings of the state of the science and informed by spurious claims within the press.[125]

However, certain scenarios, such as the misuse of synthesised select-agent viral-genomes by terrorists, have been taken seriously enough to warrant some form of response and have even become key conceptual factors shaping the design of policy. A case in point being industry screening in order to prevent terrorists from ordering 'dangerous' genetic material from select-agent organisms. Many of these scenarios have also been reproduced by non-proliferation and national security circles as accessible exemplars, by academics and institutions involved with dual-use governance. The table on the next page characterises some prevalent misuse scenarios which have been discussed within policy documents, as well as raised in my own interviews with policy experts and scientists (many of whom have transatlantic institutional links) in both the US and the UK.

[125] Interview on file with Author: Leading US Scientists in the Synthetic biology community.

| Scenario | Description |
|---|---|
| Terrorist misuse | Terrorist group use technologies and scientific knowledge to synthesis select-agent. |
| Bad scientific practice | A scientist, through bad biosafety practice, allows dangerous pathogen to escape lab. |
| Criminal misuse of technology | The use of new techniques for the development of illegal drugs such as LSD. |
| Prank by student | Student releases modified organism which cause harm or public panic. |
| State-level misuse | Scientists directly/ indirectly contribute to a covert bioweapons programme. |

**Table 5 An overview of the key scenarios of synthetic biology misuse in the US and the UK**

An interesting observation which emerged within this thesis is that in both the US and the UK is that the NEST domain has had fundamental impacts of the scope of synthetic biology which has been discussed as dual-use issues in public forums as well as within the scientific community. However, the US and UK differ in some important ways in relation to the extent to which such concerns have translated into policy responses. These responses have involved changes in national legislation, stakeholder policy as well as novel voluntary governance initiatives. Below, the scope of policy responses within the US and the UK are outlined and compared.

Controlling Foundational Synthetic Biology Technologies

There have been two key ways in which emerging polynucleotide synthesis capacities have been understood to challenge national regulatory systems by policy makers. First, this development has been understood as a potential challenge to biosafety systems addressing Genetically Modified Organisms. In a US, following recommendations from the NSABB, NIH guidelines were updated to explicitly include synthetic as well as recombinant nucleic acid molecules, as well as organisms which contain these molecules. This was in order to close a loop-hole in the existing guidelines which covered modified genetic material and organisms which had been produced recombinant methods, but did not explicitly address those produced by synthetic means. In contrast within the UK, this development was not understood to challenge existing UK and EU level biosafety oversight systems. A second development has been the emergence of screening-standards within the polynucleotide industry. In the US, the government established an inter-agency process to develop screening standards following the lead of industry. The screening standards, which the government developed, addressed double-stranded polynucleotide sequences only meaning that the standards did not address shorter, single stranded sequences (i.e. less than 200 nucleotides) despite concerns that it was possible to synthesis pathogens using these sequences and that developments in synthetic genomics would make this process simpler and cheaper in the future.[126] In contrast, within the UK, the government has only held a publicly known cross-departmental meeting on the issue of short, single-stranded sequences. This came in response to the Guardian article which reported on how a journalist had ordered a fragment of *Variola* genetic material from a polynucleotide synthesis company. Such distinctions are rather academic, however, when one considers final outcomes. In both the UK and US, longer double-stranded DNA segments which are only produced subject to screening in those

[126] It is worth noting however, that under the screening guidelines fragments as small as 200bp within larger strands are still subject to screening.

companies which have adopted screening practices - whereas the shorter strands, which are currently primarily used in research, are not.

It is also worth reiterating that while polynucleotide synthesis technology has been discussed in terms of control, other technologies associated with the field of synthetic biology have as of yet received little societal attention as sources of dual-use concern but have been discussed by experts. This includes technologies and associated techniques which underpin; advanced genetic manipulation, such as DNA shuffling, (Epstein 2012); protein engineering (Jefferson 2012); as well as projects which aim to develop libraries of categorised biological parts (Kelle 2012a). Such technologies could also foreseeably lead to the development of new means to synthesise toxins, as well as to the generation of new toxins, or pathogens.

Designing safeguards into technology

Another type of policy response to dealing with the challenges raised by synthetic biology, is to engineer safeguards into biotechnologies and products (Moe-Behrens, Davis, and Haynes 2013). At SynBERC in particular, this approach to managing risks has become very prominent, however there is much less attention to the idea in the UK. In relation to dual-use issues, there has been no discussion of the viability of this approach for addressing dual-use risks. Although it appears likely that such approaches may be considered in security and proprietary terms in the future. It is worth noting however, that these potential governance initiatives will have comparable scope to that of laboratory biosecurity and biosafety. This is in the sense that it will potentially discourage against the theft and diversion of genetically engineered life forms for hostile purposes, but will not address the prospect of state level programmes. There has also been limited discussion of the potential for regulating and licencing polynucleotide synthesis technologies within the US in particular, although no such action has been forthcoming.

In both the US and UK, local-level biosafety and ethics review has been the dominant way in which research has been assessed for dual-use concern. Added to this, within the US there is evidence of higher level dual-use review occurring within the NIH, as well as of local level community driven biosecurity initiatives, which have involved collaboration with security experts and regulators. Within the UK, this latter form of engagement has been more limited. In both the US and UK the focus of dual-use concerns remains upon the misuse potential of single experiments. However there remains an absence of agreed risk assessment criteria for identifying dual-use research.

It is also apparent that there is a higher level of awareness of many biosecurity concerns within the field of synthetic biology as compared to other fields, as a result of awareness-raising and education activities at national level (which includes those within the amateur biology community). Such awareness is of central importance if the prospect of self-governance is to be taken seriously. However, in both cases there is a requirement for institutional developments outside of the field of synthetic biology if review processes are to be more comprehensive and have an impact on the practice and direction of research. There is evidence in both the US as well as Europe[127] of the institutionalisation systems of dual-use use research review; this incudes, for example, review by funding organisations. However, there has yet to be a comprehensive analysis of how these review processes actually function across institutions in national contexts.

Added to this, synthetic biology innovation presents challenges which go beyond the scope of these review systems. For example industrialisation will lead to a host of 'technical' challenges at national level, related to safety and security. It is also likely that R&D with be carried out in an increasing range of intuitional contexts as private investment increases -

[127] In the Netherlands in particular.

such R&D may be subject to different ethical and regulatory environments. Such developments will also create challenges at international level as new types of biological and chemical development and production facilitates within states (which may potentially be utilised for hostile purposes) emerge.

### 7.3 The Politics and Practice of Dual-Use Governance

A key narrative of dual-use governance within both the US and the UK is that of optimism, under performance and renewal in the faith of the prospect of up-stream, participatory and anticipatory governance. The primary and immediate responsibility has fallen to ELSI thrusts of synthetic biology institutions. However, the ELSI community has faced severe political obstacles, from within, and external to, the scientific community. This created a type of political over-hang, where dual-use scenarios as well as solutions could be imagined, but implementation of such responses was unfeasible without broader support from government and other stakeholders. During analysis the NSABB working groups on synthetic genomics and synthetic biology were also identified as key components of the US NEST domain; an institution which is without counterpart within UK dual-use politics. To some extent this institution has both reflected and has facilitated the emergence of US political capacity to address dual-use issues associated with synthetic biology. However, this institution has also operated in a similar political environment to those within the ELSI community. This is in the sense that the implementation of NSABB recommendations is dependent on other actors, in particular at federal level.

This being said, within both the US and the UK there is evidence of local ELSI initiatives targeted at the emerging synthetic biology community, as well as the associated amateur community, which have sort to impact upon innovation practices in the name of biosafety and biosecurity. Primarily, this has been constrained to educational and awareness-raising

initiatives targeted at participants of the international IGem competition, as well as the amateur community. This has been the case in both the US and the UK. Within the US, this has also been supplemented by the development of collaboration between the FBI WMD directorate and the amateur and synthetic biology communities. Added to this, within the US there has also been the addition of 'hotline' initiatives. In neither the US nor the UK however, is there evidence that these activities have constituted broader transformations in the relationship between the field of synthetic biology and regulatory institutions in the name of security.

### 7.3.1 The Prospect and Significance of 'Top-Down' Regulation of Scientific Practices in the Name of National Security

There were stark contrasts between the US and the UK in relation to the significance of the prospect that the government may engage in an expansion of its activities directed at the governance of new and emerging life science, beyond that of improving existing enforcement of laboratory biosecurity. This would involve tighter controls on the dissemination of both information about cutting-edge research and technologies. Within US the sweeping changes under new homeland security meant a co-ordinated federal response to dual-use has been a prominent spectre on the horizon, particularly within the scientific community. This has been reflected each time dual-use concerns have come to public attention. However, as of yet, this response has not materialised. In contrast, within the UK, the prospect of such response is the name of security is taken less seriously. Instead, backlashes in the name of safety have been more significant, but have had little direct relevance to the politics of dual-use issues within the UK.

Comparison of UK and US experiences reveals that the prospect of government regulatory intervention has had two effects on the discourse. First, it has tended to lead to the

presentation of a ‘top-down’ verse ‘bottom–up’ presentation of oversight options. In reality, of course, most systems of oversight advocated would include at least an element of both. This dichotomy has been particularly prevalent within the US, as a result of the antagonistic state of ELSI politics surrounding the field of synthetic biology, but also because of the pre-existing politicisation related to biosafety and biosecurity regulation. This is in contrast to the UK, where, in the absence of the prospect of state level response, there has been substantially less debate about the issue and less polarisation.

The second consequence of the prospect of federal intervention within the US has been to motivate and galvanise responses from the polynucleotide synthesis providers and the scientific community. Within the US, it was in the context of a potential federal response that aspects of the synthetic biology community began to consider and develop technical solutions to security challenges posed by the emerging synthesis industry. Secondly, the prospect of federal oversight was also utilised rhetorically to help motivate early community involvement with other biosecurity policy initiatives. This also had knock-on effects within the European and UK discourse, as it meant that the dual-use use issue was initially framed as a poorly defined risk requiring a practical solution, rather than an issue which primarily required public education initiatives to downplay concerns.

### 7.3.2 The Impact of Systems of Anti-Terrorism Oversight on the Practice of Innovation within the Field of Synthetic Biology

There is little evidence that anti-terrorism policy has had immediate impacts upon innovative practices in response to concerns about synthetic biology. In both the US and the UK, outreach and education have been the main means through which national security institutions have engaged with the dual-use issue. In the US this has been through the FBI WMD directorate. In the UK, there is some evidence that NaCTSO is also considering

pursing educational initiative, although there has been no specific intuitive directed at the field of the field of synthetic biology.

This is not to suggest however that aspects of the emerging field of synthetic biology will not be made subject of anti-terror regulation in the future, or else be used as further evidence for the need to develop existing systems of oversight. In relation to the first point, in both the UK and the US, bioterror scenarios have already motivated cross-departmental discussions of the emerging polynucleotide synthesis industry. In the UK, these discussions have primarily resulted in the appropriation of existing biosafety regulation in the name of security, as well as the adoption of a wait and see stance. Since this time, developments within the European gene-synthesis industry have not motivated further publicly known responses from government. These developments include the growth of support for increasing UK industry capabilities to synthesise much longer polynucleotide sequences as well as the emergence of a European industry channel of policy development. It seems likely that any future discussion which could be sparked by a press scare for example, would need to take these developments into account. Within the US, the prospect of terrorist misuse of gene-synthesis capabilities was enough to motivate a more substantive federal response, in the form of detailed federal guidelines for industry. However, this response followed largely in the wake of pre-emptive industry engagement misuse of the issue. Once again, it seems likely that tougher or broader action from government may be called for if further press scares, or expert concerns emerge in relation to this or associated industries.

### 7.3.3 The Externalisation of Concerns about Biodefense and the Arms Racing Dynamic

In chapter two, it was argued that developments at national level within public health and biodefense policy were potentially important to understanding the governance of techno-

scientific fields such as synthetic biology. This was for two primary reasons. The first was that there had been higher levels of investment into DURC of concern within the US under biodefense initiatives. This suggested that DURC may have been a greater priority within the US and had knock-on effects for the field of synthetic biology. The second reason was that that some biodefense research was politically contentious, especially in the US. In particular, there had been debate about the militarisation of research agendas, the issue of threat characterisation research, as well as concerns about the safety of US biodefense labs- in public, scientific, non-proliferation as well as government circles. These concerns had been accompanied by a broader set of debates about necessity and effectiveness of the US biodefense programme (Kelle, Nixdorff, and Dando 2012, chap. 5). This situation could be contrasted to the UK public health domain, where such issues had been absent, primarily because of the absence of a politicised relationship between the public health and security community, as well as the absence of a significant biodefense research imperative.

In analysis, it became clear that there were no significant differences between the US and the UK with regard to the emergence of policies directed at the identification and management of dual-use risks associated with state-level misuse of the field of synthetic biology at domestic-level, that were publicly known. In fact, in neither case were there significant activities or channels of policy development in place to deal with this issue. This was quite surprising considering the amount of attention received by the field of synthetic biology in US and UK submissions to the main international body that deals with these issues (the BTWC) since 2006 as part of working papers and confidence building measures. Indeed, in many ways synthetic biology has become an exemplar of de-skilling and globalising dynamics in the context of the BTWC regime.

The absence of attention to state misuse scenarios was also surprising considering the increasing military interest in the field with both the US and the UK.[128] This is not to argue that current work crosses the line into offensive research, purely by virtue of military involvement, or because of the nature of the research. Indeed the majority of this work would not be considered to be of misuse potential by most if not all of those actors who have been involved with dual-use politics over the previous decade. This because the publicly known investment into the field has not been directed at grey area bio-defensive work - instead projects have tended to focus on more efficient production of conventional military materials and biomedical interventions, or else been used to fund more foundational technologies. Instead, what should be considered surprising is the absence of discussion of the potential of state-level misuse raised by the prospect of the militarisation of aspects of the field in the long term.[129] Specifically, that early military investment could potentially become the preface to more aggressive investment which pushes up against current bans on the development of biological weapons, or else undermines the BTWC regime by reducing states' faith in the idea that other states are not willing or able to pursue biological weapons as part of a viable defence strategy. It is possible to argue that this is a more systemic issue related to the absence of an international compliance verification systems in the BTWC, and it will be interesting to see whether Synthetic Biology receives more attention in this respect as the Organisation for the Prohibition of Chemical Weapons (which does have a verification system) begins to grapple with the field.

### 7.4 Towards National Styles of Dual-Use Governance?

128 Within the US this has been reflected in investments by DARPA, DTRA as well as Office of Naval research. Within the UK this has also been reflected in investment by DSTL

129 A point made for example by In an interview with a BWC official( Dr Piers Millet) (Newswire 2012)

In both the US and the UK the continued prominence of anticipatory and up-stream framings of dual-use techno-science were dependent on constant reproduction on the NEST agenda. Within the UK dual-use concerns about the techno-science of synthetic biology actually largely pre-dated substantial investment into the field. It is worth remembering that the first major UK investment into establishing a synthetic biology community occurred after a conception of dual-use techno-science had already been established within the US. An important consequence of this was that early framings of the dual-use issue articulated within early EU and UK reports on synthetic biology were influenced by US framings of the issue. In particular, they placed the emphasis on the need for concrete risk evaluation and management response to the problem. However, this belied low levels of interest within the UK synthetic biology NEST domain in relation to dual-use issues, as well as the government. In contrast to the US, these early articulations did not occur alongside political efforts within and outside the community to engage in anticipatory policy-focused discussions. This meant that dual-use discussions, when they did take place in ELSI forums, tended to be speculative rather than tied to specific dual-use concerns raised by the field in a UK context. As a result, there would be less discussion of need to develop political and technical capacity to address the dual-use challenges posed by the techno-science, as compared to the US.

In the absence of root and branch changes to the practice and governance of techno-science biosafety governance rationalities have been fundamental within the US and UK. Specifically these frames were essential in delineating the scope of the innovation practices and artefacts of the techno-scientific field of synthetic biology which were discussed as governable problems. For example within the UK, faith in the existing biosafety system meant that agreements on the scope of the dual-use problem was closely linked to the range of dual-use scenarios that existing biosafety systems could foreseeably address. Within the US, this was

also the case with the identification of institutional biosafety review as a centrepiece in the US response to dual-use issues by the FINK report. The NSABB also explicitly supported the adoption of this model for state funded aspects of the synthetic biology community. In both cases this has placed the emphasis of dual-use governance upon the review of single projects and experiments at institutional-level as a key approach in dealing with dual-use issues. This has had fundamental impacts upon how the 'problem' of dual-use research has been conceived in national contexts. Specifically, it has led to the predominance of a framing which places local-level scientific and ethical review as central to defining which type of research constitutes a reasonable dual-use concern (Edwards, Revill, and Bezuidenhout 2013). This externalises those aspects of the dual-use issue, including trends in the practice of science, or broader questions about the trajectory of research from assessment as well as broader transformations in innovation practices.

Such a situation has not seriously dampened the optimism of the emerging coalitions of social scientists, scientists and industry embarking on the next stage of the field's development within the UK and US about the prospect of pre-emptively engaging with the dual-use issue through the application of existing national governance practices. However, it is likely that in relation to the field in both the US and the UK, policy will continue to be made reactively and on the hoof, driven largely by press scares, scandals and disasters, with waxing and waning levels of attention from government departments reflecting this.[130] As has already become clear, attempts to transform the relationships between innovation and governance in the UK at SynBERC, as well as the more modest attempts within the UK synthetic biology networks, represent failures to establish institutionalised support of anticipatory policy-making.

[130] As one prominent policy shaper in the US stated, with regard to the engagement of the security community, after the establishment of the NSABB in response to concerns about bioterrorism between 2001-2004 'over time most of the security people became much less engaged in the process'. On file with Author.

To date, only a very narrow range of scenarios and artefacts are currently subject to the type of politics and practices expected within a risk governance regime. Specifically, this has involved a focus on securing physical controls over certain biological materials in order to ensure against terrorist diversion as well as curtailing the circulation of specific experimental findings with obvious and immediate dual-use applications. This has meant that dual-use concerns about broader trends in innovation and scenarios involving state-level misuse which have been raised in the ELSI and arms control community remain excluded from such discussions and processes.

A key contrast between the US and the UK has been that there has been greater attention to the issue of polynucleotide synthesis at national-level from the government within the US. However in the US, UK and Europe more generally, industry has taken the lead in the development and implementation of governance through the development of harmonised screening standards. Within the US, attention within the academic research community resulted in the emergence of a public consensus within the Sloan Report and NSABB report, which emphasised the role of industry and the scientific community in the development of oversight of polynucleotide synthesis. Within the UK there has been less evidence of processes of consensus-building in relation to the issue of polynucleotide synthesis at national-level involving government institutions. There is evidence, however, that through its actions, the ISAB has ensured industry-led policy development and implementation in this issue area at a European level, if and when government departments review this area. In the coming years it will also be interesting to see the extent to which other comparable service providers (such as those which provide tailored biochemical systems or even organisms) also end up taking the lead in the development of industry biosecurity standards.

### 7.5 Conclusions

The process of analysis and comparison has led to a series of conclusions about the nature of the prospect of dual-use governance at national level within both the US and the UK. Most significantly, the work has highlighted the extent to which rhetoric of risk management belie low-levels of engagement by key regulators in the cases analysed, and has outlined the factors which have driven and frustrated such engagement. Comparison has also demonstrated the extent to which national capacities to imagine dual-use issues out run the ability of institutions to comprehend, and, where necessary, respond to such fears. This work has mapped out, in detail, the discursive and political mechanisms through which this has manifested in national contexts. Secondly, analysis has led to a clearer understanding of the significance of the various domains of governance in the politics of dual-use governance at a national level. In particular, it has highlighted the significance of the NEST domain in articulating dual-use concerns and the prominence of the biosafety domains in the identification of which aspects of these broader concerns require a response at national-level. Analysis has also revealed that the anti-terrorism and public health domain has actually played a less significant role than expected in relation to the governance of the techno-science of synthetic biology, in both cases. This finding was particularly surprising in relation to the US, as there had been an expectation that the politics and practices of US anti-terrorism and bio-preparedness would have had a much larger impact on the politics and governance of dual-use techno-sciences in the US as compared to the UK. It was argued that this outcome primarily reflected the externalisation of more forward-looking concerns about trends in innovation as well as concerns about development of biological weapons by states, from the dual-use discourse in both the US and the UK. The externalisation of such concerns reflected a trend among key regulators within both the US and the UK to only address dual-use issues

*ad hoc* and only then in the face of significant public and stakeholder attention to a given issue.

In both the US and the UK, this style of politics has resulted in the in the situation that Kelle (2012b) refers to as 'patch-work precaution'; this is in the sense that only a narrow range of possible interventions (effective against a narrow range of possible misuse scenarios), are in-place along the pipeline of innovation. Potential interventions range from international treaties at the level of the state, down to laws and standards for individuals. Currently these safe-guards, where they are present, are primarily directed at controlling specific pieces of technology and laboratory biosafety. Politically speaking however, the patch-work of precautionary activities has also been associated with a patchwork of reassurance and deferral activities. These activities have sought to reassure the public that dual-use issues are already being dealt with by existing systems, are else will be manageable in the future.

In the following chapter, there is a recapitulation of these findings in the context of the overall purposes of this thesis as well as discussion of their significance for the study of dual-use governance.

# Chapter Eight: Conclusions and Future Research

## 8.1 Introduction

At the outset of this thesis, the following question was asked:

> *To what extent are the conceptions, practices and politics of security relevant to understanding the governance of dual-use aspects of new and emerging science and technology at national level in the UK and in the US?*

The motivation for asking this question stemmed from a desire to develop a clearer understanding of the political processes which have underpinned the emergence of dual-use governance within the US and the UK. This interest was largely driven by the observation that claims about security politics, security thinking and the value of security were central to the way in which dual-issues had been conceptualised in both academic and policy literature. One example of this dynamic is the presentation of the dual-use issue as an 'ethical dilemma', involving a balance of principles relating to the imperatives of security with principles related to innovation, such as the freedom of intellectual enquiry and the right for society to benefit from scientific progress. Another example is the dichotomous presentation of dual-use governance options which pit restrictive models of oversight driven by national security actors against governance approaches driven by the scientific community. Within the context of this thesis, it has been demonstrated that such dichotomies represent a relatively crude understanding of the politics of dual-use issues. They therefore became focal points of this thesis, which led to findings which are relevant to both dual-use governance theory and securitization theory.

## 8.2 The Significance of Findings for Dual-Use Governance Theory

In chapter two, a set of underlying drivers were identified which could go some way to explain the modern manifestation of dual-use issues, specifically:

> a) The emergence of fears about terrorism, in particular bioterrorism, in both public and policy circles and specifically relating to the threat from non-state actors.

b) The dominant assumption about the fast pace of scientific and technological development associated with the life sciences.

c) Changes in the relationship between science and democratic societies.

However, it was argued that identifying such drivers did not constitute a complete explanation for how issues are governed in national contexts, and why. In chapter two, it was stated that such an explanation required the identification of important factors within the policy development process in each case.

In chapter three, securitization theory was taken up as suitable departure point for the development of an analytical framework which could help to identify such factors. Security was an interesting departure point, not only because of the terms prevalence in in discussion of the ethics and politics of dual-use issue, but also because the US and UK reflected different approaches to addressing the dual-use challenge, and this distinction was often made in relation to the involvement of national security institutions.

In the chapters that followed, specific factors were identified, and a thematic overview of these findings was provided. In the following sections the implications of these findings are considered.

### 8.2.1 Misuse Scenarios and Dual-Use Governance

Within this research, emphasis has been placed on the processes through which misuse scenarios have been imagined, gained policy significance and informed policy responses. Publicly accessible misuse scenarios have been associated within rallying calls to transform and amend existing regulatory systems. This has been reflected in the US in particular, where dissatisfaction about the US system of laboratory biosafety oversight voiced within some aspects of civil society has been a key driving force behind the continued discussion of the risks posed by select-agent research. At times, dissatisfaction with international regulatory

frameworks, specifically the BWC, have also led to concerns about biodefense research crossing the line into offensive research, or else stimulating arms racing dynamics within national dual-use discourses.

However, it is not only imagined scenarios which inform the scope of dual-use issues under discussion. Understandings of existing regulatory structures, such as laboratory biosafety and laboratory biosecurity have also been key in enabling actors to distinguish between dual-use concerns which can be conceivably addressed as risks, and those which cannot. The NSABB understanding of the scope of dual-use issue in particular, with its focus on local level review, has become central not only in how dual-use issues are governed, but also in how new dual-use issues are being identified.

Taken together, these findings point to the idea that while it is the actors rather than the analyst which define dual-use concerns, analysts can help to explain why some dual-use concerns attract attention as governable problems and others do not. In addressing this question, the analyst can not only discern which issues actors take seriously and why, but also which key factors set the limits of political feasibility of responses to dual-use concerns at national level.

### 8.2.2 Dual-Use, Security and the State

While it is important for analysts to escape the false dichotomies of 'top-down' verses 'bottom-up' governance when thinking about the governance of dual-use issues, it is worth remembering that this distinction still has significance in dual-use politics. During analysis it became clear that the prospect of top-down governance maintained a significant role in how publics and even many scientists and policy makers understood the politics of dual-use issues, primarily in the name of security in the US and of safety in the UK. Nonetheless, it

has been demonstrated within this thesis that there are various reasons that the prospect of top-down governance may be overplayed in the context of dual-use discussions. First, there may be incentives for actors wishing to stimulate some sort of response to dual-use issues within the scientific community to emphasise and perhaps even exaggerate the prospect of top-down regulation. Second, certain scientific institutions have a tendency to react to the prospect of state involvement by demonizing the prospect of further regulation.

However, for various reasons it is unlikely that the state will engage in the pre-emptive regulation of dual-use life science research and technology. First, such issues are rarely conceivably addressed through the application of existing technologies of control. In the US, for example, the discussions of 'nuclear style dual-use controls' reveal the extent to which traditional controls on materials and technologies were widely understood to be unsuitable for the oversight of life science research. In the absence of an acceptable transferable model, it is understandable that there is sometimes little political interest in a complex and politically charged issue area. In this context, it is unsurprising that the Executive look to industry and the scientific community to develop systems of oversight.

Another key finding within this research is that concerns identified and expressed within the ELSI domain which cannot be dealt with through applying or modestly modifying existing systems of governance can quickly become externalised from the discourse. This means that the emergence of policy responses to these issues is largely at the whim of broader historical and political factors. For example, a key explanation for the emergence of dual-use concerns about synthetic biology in the US context is the sweeping changes under new homeland security in the early 2000s, which meant a co-ordinated federal response to dual-use was, for a while at least, spectre on the horizon, particularly within the scientific community. This fear has been reflected each time dual-use concerns have come to public attention. In contrast,

within the UK the prospect of such a response in the name of security is taken less seriously; instead, backlashes in the name of safety have been more significant.

This suggests that, while lessons may certainly be learned from oversight initiatives which have reached the implementation stage, such developments should not mean that we forget the political obstacles to policy development. In particular, it is essential to remember that the state, and its regulatory bodies, plays a fundamental role in the fate of 'bottom-up' initiatives. For example, the prospect of intervention by regulatory bodies can motivate action, and financial and other forms of institutional support can validate bottom-up initiatives and support successful implementation. However, it is also clear that such bottom-up initiatives tend to be heavily truncated in scope, focusing primarily on galvanising existing governance structures such as laboratory biosafety and biosecurity.

### 8.2.3 The Prospect of Anticipatory Governance

Within the case studies it became clear that anticipatory governance can involve the pre-emptive development and institutionalisation of various aspects of risk pre-assessment of dual-use issues. To recap, risk pre-assessment involves the four different types of activity problem framing: systematic searches for new hazards, the identification of relevant systems of oversight, and the adoption of scientific criteria and procedures for risk assessment. This research has demonstrated the extent to which it is possible to distinguish which of these goals have been pursued and reached in national contexts in relation to specific dual-use issues. In the cases of the US and the UK, for example, the predominant role of the NSABB framing of the problem of dual-use research was identified. It is also possible to argue that there was greater evidence of systematic searches for new risks, reflected in the work of the Sloan report and NSABB. A point worth noting here is that such 'systematic searches' are likely to systematically exclude certain concerns from consideration, as they tend to be

focused on immediate challenges, as demonstrated in the Sloan report in particular. Dual-use research and gene-synthesis technology within the US and Europe can also be contrasted in relation to the significance of scientific conventions for risk assessment. With regard to gene-synthesis screening, conventions were developed which focused primarily on gene-sequences homology with select-agent pathogens. This quickly became a metric which all stakeholders could agree on, even if there remained some disagreement on the specifics of implementation. In contrast, the issue of dual-use research remains a matter of contested expert judgement, rather than 'objective' technical assessment. Such ambiguities extend well beyond the field of synthetic biology, and have been reflected most recently in discussions about H5N1 avian influenza gain of function research (Edwards, Revill, and Bezuidenhout 2013). It is likely, however, that in the near future, certain lines of research and emerging laboratory techniques currently associated with the field of synthetic biology will become embroiled in comparable debates, particularly in research involving pathogens.

It is worth noting that ambiguities related to dual-use research manifest in both the US and UK discourses; however, a key distinction is that the issue has received a much greater airing in the forum that the NSABB has provided. This suggests that the existence of such institutional focal points are also important to thinking about the governance of dual-use issues in national contexts. This work has also demonstrated that 'official' institutions such as the NSABB can have a political significance which can extend beyond its primary purpose of advising government. The position of such bodies can all too easily become conflated with the position of the Executive within political debates. However, as has become clear in this research, not only has government tended to follow a few years in the wake of its blue-ribbon institution, it has also been selective about which policy recommendations to implement. For those that would like to see a more prominent role for such expert panels in dual-use

governance in the US, EU or elsewhere, there are valuable lessons to be learned from this institution. This includes, for example, the role that such institutions can play in validating industry and academic initiatives which by and large run before government engagement.

Another key observation, is that anticipatory discussions are informed not only by claims about the potential of science and technology, but also by assumptions about the political feasibility of responses to a given concern. In particular, it is worth bearing in mind that those involved in anticipatory governance may have incentives, as well as biases, which lead to the to the communication of narratives of transformation. Such claims, however, tend to under-emphasise the extent to which governance initiatives in these fields, while often novel and inspiring, are subject to a broad and entrenched set of challenges. Such challenges, for example, have hampered attempts to move governance 'up-stream' within the innovation process through transforming human practices in the context of SynBERC. It is essential, then, not only to focus on the question of why such initiatives emerge, but why they don't, and the extent to which such initiatives can be understood to have resulted in comprehensive transformations of governance in relation to a specific issue. A key part of such analysis is therefore focusing on the failings and limitations, as well as the promise, of such initiatives in order to stay sober about the scope and feasibility of responses to dual-use concerns in other national contexts, or in relation to other technologies.

### 8.3 Dual-use Governance and Securitization Theory

Dual-use governance has proved an interesting issue area for the application of securitization theory. First, this research has drawn attention to the role of epistemic communities and scientific consensus positions on given issues in the context of complexity and uncertainty (Buzan, Wæver, and Wilde 1998, 72–73). In particular, this work has emphasised the fundamental impacts of the emergence of these factors on agenda setting and problem

definition. Added to this, the work has drawn attention to the idea that systemic risks are made governable rhetorically with reference to complex webs of collaboration between institutions in the development and implementation of risk governance activities. This includes, for example, bio-preparedness models of governance which have developed in the US and Europe. However, the work also draws attention to the idea that such collaboration faces a series of political challenges, particularly in the context of anticipatory modes of governance which attempt to deal with challenges beyond the scope of existing risk management structures.

Second, this work has outlined that it is in this context that actors (including state and non-state institutions) engage in two key modes of engagement with security politics. The first is the *primary* mode, which involves engagement in activities designed to set the rules for future policy making processes in relation given issue. This includes, for example, deciding which institutions are in charge of developing and implementing policies, and the nature of collaboration between actors within these processes. Within this work, it has been argued that the epistemic communities embodied in the NSABB and Sloan report processes, for instance, have been central to such processes.

The other mode of engagement is *secondary*, which involves engagement in the context of agreements about the overall process of policy development. Within this mode of action, actors seek to impact directly on the policies which are being developed and implemented. This may include initiating, advocating, facilitating or resisting specific initiatives.

Third, this work has outlined the extent to which policy models are useful to those who study processes of securitization in the context of systemic risks. In chapter three, it was argued that these models could provide focus, structure and limits within analysis, which are of central importance in interdisciplinary studies, as well as in multi-level approaches, and that this

could help the analyst to identify which activities, discourses and actors are and are not relevant with regard to policy outcomes.

It is certainly the case that these models performed these roles in two important senses. First, they provided a central narrative for the life and death of single initiatives and policy proposals. For example, they allowed for the exploration of the extent to which forward-looking oversight proposals have been rejected within political and policy streams within the US. A case in point is recommendations made by the NSABB in relation to synthetic biology research and technology, which have often struggled to garner federal US support. Another example was the 2004 bio-hazard non-proliferation proposal of George Church, which was dropped in favour of other governance options developed within the academic channel of polynucleotide synthesis policy development.

It was also argued in chapter three, that such policy models could provide a straightforward institutionally, historically and politically situated 'environment' for discourses and 'speech-acts' to occupy within an overall process of securitization. Such claims were made in the context of the concern that analysts studying securitization processes who rely on a linguistic approach may struggle to adequately account for the socio-historical context of speech acts, and to sufficiently trace the impact of such acts on policy outcomes. Simply put, it was argued that some approaches focus much more on those 'speaking' security in relation to an issue, and much less on those actually developing and implementing security policy. During the analysis process, policy process models provided a framework to help understand why actors were speaking security in some contexts, and what the actual implications of this was for emerging policy. A key example related to the NEST domain, where the scientific community, as well as associated social scientists, have been identified as a first line of defence in dealing with dual-use issues. Placing these assertions in a broader political

context, however, revealed the extent to which these claims were contested, as well as the extent to which such assertions often belied low levels of action. Further to this, reasons were given to explain why NEST initiatives were struggling within both a US and UK context to transform innovation practice, as well as to encourage key regulators to engage pre-emptively with broader dual-use concerns.

Finally, this research also demonstrated the extent to which the questions of 'why' actors engage with securitization processes could be addressed within analysis. To recap, in section 2.6, it was argued that the issue of intentionality was largely neglected within predominant approaches to the study of securitization for various theoretical and methodological reasons. In response, a new means of conceptualising intentionality in the study of securitization was outlined. Specifically, it was argued that there were two types of explanations for the behaviour of actors within security politics. The first related to *pragmatic actions and interests*, which involve identifying the context of specific actions, such as publications, or lobbying at a specific event. In this thesis, for example, some of those interviewed identified specific actions with which they had engaged in order to alter specific policies. Such actions, however, can also be explained with reference to *institutionalised practices, interests, values and favoured policy responses*, which point to a broader underlying political landscape which informs pragmatic actions. This latter set of explanations can also highlight more generalizable findings which highlight the lessons provided by the analysis of specific episodes and initiatives in relation the issue area. This includes, for example, the types of policy are and are not feasible in the existing political context. However, this work has also drawn attention to the idea that changes in the political environment, such as those which resulted from the terrorists attacks in the early 2000s, can have fundamental impacts in motivating action by freeing up resources, and creating a sense that that dramatic changes in a

given policy area are possible. There is no guarantee, however, that future transformations in the governance of dual-use synthetic biology will be motivated primarily by the threat of federal responses to terrorism; in fact, it appears that market forces will play an ever increasing role in the field as it becomes more industrialised.

### 8.4 Future Research

The majority of research into dual-use aspects of synthetic biology and indeed the dual-use issue more generally has sought to make observations relevant to policy makers or to aid the implementation of policy initiatives. A potential risk of such work, as with all policy driven research, is that it becomes easy to focus on addressing policy challenges within the existing political environment, rather than questioning the environment itself. My aim within this work was to engage in both types of activity, and I hope that this apparent within the work. Below I highlight some key questions that the process of conducting this research has raised.

The first relates to the lessons which can be learned about dual-use politics as the field of synthetic biology develops. In particular, it seems reasonable to assume that over the coming decade, the field of synthetic biology will produce a range of foundational technologies and techniques which will become fundamental to new practices of innovation, as well as in the production of new products. A key question will be the extent to which early dual-use discussion and initiatives translate into later-stage initiatives which continue to have discernable impacts upon the industrialisation of aspects of this field. This includes, for example, ELSI components of future synthetic biology research initiatives such as the recently announced EU wide SYNENERGENE[131] project. It also includes national level initiatives which focus on supporting the translation of synthetic biology research for applications, and which incorporate synthetic biology into plans for the emerging bio-

[131] http://www.synenergene.eu/.

economy; this has already been reflected in The White House US National Bio-Economy Blue Print, which was produced in April 2012.

This question is particularly important, and challenging, as the field of synthetic biology is the first techno-scientific field to address contemporary dual-use concerns so early in its development. Such research could have significant implications for understanding how field specific early- and mid-stage ELSI dual-use initiatives should be designed and implemented in the future if they are to ensure regulators and other stakeholders adequately anticipate and engage with advances in science and technology.

A question relates to the consequences of developments in the field of synthetic biology for thinking about future dual-use concerns. It is likely that over coming decades, experiments in dual-use governance which have occurred in relation to the field of synthetic biology will be important in discussions of other dual-use issues. This not just in the sense that development will have rhetorical significance as an accessible exemplar in policy circles, but also in the sense that developments in the field may have contributed the new epistemic communities and institutional relationships and capacities. In essence, then, this issue involves questioning the impact of synthetic biology dual-use governance initiatives on the governance of the dual-use life sciences and biotechnology more generally. This may, for example, include the spread of specific approaches developed in the field of synthetic biology to other fields and national contexts.

The third question relates to the significance of national experience in governing dual-use aspects of synthetic biology for the governance of dual-use aspects of life science innovation at an international level. In both the CWC and BWC there exists a requirement for state parties to take into account the impact of advances in science and technology upon the

implementation of the convention, including in relation to developments which could contribute to the prospect of misuse. However, this work has identified many of the conceptual and political obstacles which face those wishing to develop anticipatory responses to such developments. For example, it is clear that many key regulatory institutions do not engage policy focused dual-use discussions beyond the scope of laboratory biosafety and biosecurity. This suggests that, if broader dual-use concerns about developments in the life sciences are to be taken seriously, then new institutional capacities are required. Future research could be conducted to examine the extent to which discussions at international level could usefully be informed by accounts of these national level experiences. In particular, these experiences seem relevant to discussion about the implementation of the BWC and CWC at national level, as well as to the review of scientific and technological developments which occurs within these regimes.

A further line of enquiry also developed during writing this thesis relates specifically to research being conducted on securitization. This research has demonstrated that securitization theory could benefit greatly from further engagement with policy theory, particularly in the context of analytically eclectic research which focuses on specific 'real world' policy challenges. Within this thesis, emphasis has been placed on two relatively simple heuristics: specific linear and multiple stream models of policy development. This work has also touched upon ideas which are central to several other explanatory models of policy change and development, including, those which focus on epistemic communities for example. It is apparent that the utility of such concepts to securitization theory requires further investigation, if we are interested in developing the analytical tool kit within this field.

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